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(71) Applicant (for all designated States except US): **AMPLE MEDICAL, INC.** [US/US]; 155 Chess Drive Suite 104, Foster City, California 94404 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **RAHDERT, David,**

A. [US/US]; 2127 12th Avenue, San Francisco, California 94116 (US). **MACHOLD, Timothy, R.** [US/US]; 65 Bernal Avenue, Moss Beach, California 94038 (US). **CHANG, Robert, T.** [US/US]; 3314 Haskins Drive, Belmont, California 94002 (US). **MACOVIAK, John, A.** [US/US]; 5412 Thunderbird Lane, La Jolla, California 92037 (US).

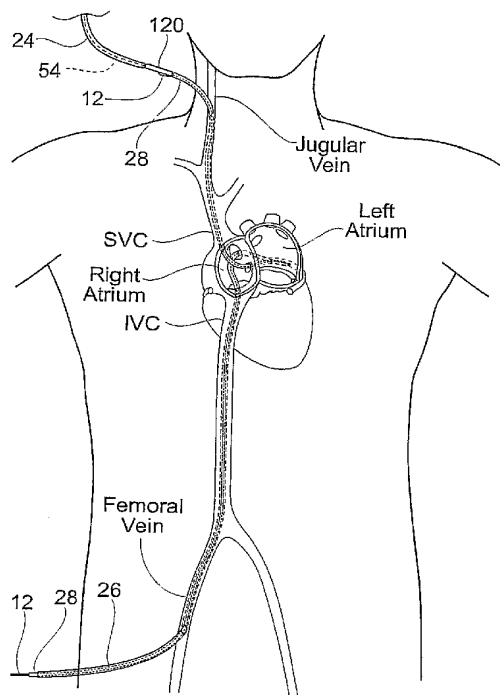
(74) Agents: **RYAN, Daniel, D.** et al.; P.o. Box 26618, Milwaukee, Wisconsin 53226 (US).

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(54) Title: DEVICES, SYSTEMS, AND METHODS FOR RESHAPING A HEART VALVE ANNULUS



(57) Abstract: Implants or systems of implants and methods apply a selected force vector or a selected combination of force vectors within or across the left atrium, which allow mitral valve leaflets to better coapt. The implants or systems of implants and methods make possible rapid deployment, facile endovascular delivery, and full intra - atrial retrievability. The implants or systems of implants and methods also make use of strong fluoroscopic landmarks. The implants or systems of implants and methods make use of an adjustable implant and a fixed length implant. The implants or systems of implants and methods may also utilize a bridge stop to secure the implant, and the methods of implantation employ various tools.



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**DEVICES, SYSTEMS, AND METHODS FOR RESHAPING A  
HEART VALVE ANNULUS**

**Field of the Invention**

The invention is directed to devices, systems,  
5 and methods for improving the function of a heart valve,  
e.g., in the treatment of mitral valve regurgitation.

**Background of the Invention**

**I. The Anatomy of a Healthy Heart**

The heart (see Fig. 1) is slightly larger than  
10 a clenched fist. It is a double (left and right side),  
self-adjusting muscular pump, the parts of which work in  
unison to propel blood to all parts of the body. The  
right side of the heart receives poorly oxygenated  
("venous") blood from the body from the superior vena  
15 cava and inferior vena cava and pumps it through the  
pulmonary artery to the lungs for oxygenation. The left  
side receives well-oxygenation ("arterial") blood from  
the lungs through the pulmonary veins and pumps it into  
the aorta for distribution to the body.

20 The heart has four chambers, two on each side  
-- the right and left atria, and the right and left  
ventricles. The atriums are the blood-receiving chambers,  
which pump blood into the ventricles. The ventricles are  
the blood-discharging chambers. A wall composed of  
25 fibrous and muscular parts, called the interatrial septum

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separates the right and left atriums (see Figs. 2 to 4). The fibrous interatrial septum is, compared to the more friable muscle tissue of the heart, a more materially strong tissue structure in its own extent in the heart.

5 An anatomic landmark on the interatrial septum is an oval, thumbprint sized depression called the oval fossa, or fossa ovalis (shown in Figs. 4 and 6), which is a remnant of the oval foramen and its valve in the fetus. It is free of any vital structures such as valve  
10 structure, blood vessels and conduction pathways. Together with its inherent fibrous structure and surrounding fibrous ridge which makes it identifiable by angiographic techniques, the fossa ovalis is the favored site for trans-septal diagnostic and therapeutic  
15 procedures from the right into the left heart. Before birth, oxygenated blood from the placenta was directed through the oval foramen into the left atrium, and after birth the oval foramen closes.

The synchronous pumping actions of the left  
20 and right sides of the heart constitute the cardiac cycle. The cycle begins with a period of ventricular relaxation, called ventricular diastole. The cycle ends with a period of ventricular contraction, called ventricular systole.

25 The heart has four valves (see Figs. 2 and 3) that ensure that blood does not flow in the wrong direction during the cardiac cycle; that is, to ensure that the blood does not back flow from the ventricles into the corresponding atria, or back flow from the  
30 arteries into the corresponding ventricles. The valve between the left atrium and the left ventricle is the mitral valve. The valve between the right atrium and the right ventricle is the tricuspid valve. The pulmonary valve is at the opening of the pulmonary artery. The  
35 aortic valve is at the opening of the aorta.

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At the beginning of ventricular diastole (i.e., ventricular filling) (see Fig. 2), the aortic and pulmonary valves are closed to prevent back flow from the arteries into the ventricles. Shortly thereafter, the tricuspid and mitral valves open (as Fig. 2 shows), to allow flow from the atriums into the corresponding ventricles. Shortly after ventricular systole (i.e., ventricular emptying) begins, the tricuspid and mitral valves close (see Fig. 3) -- to prevent back flow from the ventricles into the corresponding atriums -- and the aortic and pulmonary valves open -- to permit discharge of blood into the arteries from the corresponding ventricles.

The opening and closing of heart valves occur primarily as a result of pressure differences. For example, the opening and closing of the mitral valve occurs as a result of the pressure differences between the left atrium and the left ventricle. During ventricular diastole, when ventricles are relaxed, the venous return of blood from the pulmonary veins into the left atrium causes the pressure in the atrium to exceed that in the ventricle. As a result, the mitral valve opens, allowing blood to enter the ventricle. As the ventricle contracts during ventricular systole, the intraventricular pressure rises above the pressure in the atrium and pushes the mitral valve shut.

The mitral and tricuspid valves are defined by fibrous rings of collagen, each called an annulus, which forms a part of the fibrous skeleton of the heart. The annulus provides attachments for the two cusps or leaflets of the mitral valve (called the anterior and posterior cusps) and the three cusps or leaflets of the tricuspid valve. The leaflets receive chordae tendineae from more than one papillary muscle. In a healthy heart, these muscles and their tendinous chords support the

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mitral and tricuspid valves, allowing the leaflets to resist the high pressure developed during contractions (pumping) of the left and right ventricles. Figs. 5 and 6 show the chordae tendineae and papillary muscles in the  
5 left ventricle that support the mitral valve.

As Figs. 2 and 3 show, the anterior (A) portion of the mitral valve annulus is intimate with the non-coronary leaflet of the aortic valve. As Figs. 2 and 3 also show, the mitral valve annulus is also near other  
10 critical heart structures, such as the circumflex branch of the left coronary artery (which supplies the left atrium, a variable amount of the left ventricle, and in many people the SA node) and the AV node (which, with the SA node, coordinates the cardiac cycle).

Also in the vicinity of the posterior (P) mitral valve annulus is the coronary sinus and its tributaries. These vessels drain the areas of the heart supplied by the left coronary artery. The coronary sinus and its tributaries receive approximately 85% of coronary  
15 venous blood. The coronary sinus empties into the posterior of the right atrium, anterior and inferior to the fossa ovalis (see Fig. 4).. A tributary of the coronary sinus is called the great cardiac vein, which courses parallel to the majority of the posterior mitral  
20 valve annulus, and is superior to the posterior mitral valve annulus by an average distance of about 9.64 +/- 3.15 millimeters (Yamanouchi, Y, Pacing and Clinical Electrophysiology 21(11):2522-6; 1998).

## II. Characteristics and Causes of Mitral Valve

### 30 Dysfunction

When the left ventricle contracts after filling with blood from the left atrium, the walls of the ventricle move inward and release some of the tension from the papillary muscle and chords. The blood pushed up  
35 against the under-surface of the mitral leaflets causes

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them to rise toward the annulus plane of the mitral valve. As they progress toward the annulus, the leading edges of the anterior and posterior leaflet come together forming a seal and closing the valve. In the healthy heart, leaflet coaptation occurs near the plane of the mitral annulus. The blood continues to be pressurized in the left ventricle until it is ejected into the aorta. Contraction of the papillary muscles is simultaneous with the contraction of the ventricle and serves to keep healthy valve leaflets tightly shut at peak contraction pressures exerted by the ventricle.

In a healthy heart (see Figs. 7 and 8), the dimensions of the mitral valve annulus create an anatomic shape and tension such that the leaflets coapt, forming a tight junction, at peak contraction pressures. Where the leaflets coapt at the opposing medial (CM) and lateral (CL) sides of the annulus are called the leaflet commissures.

Valve malfunction can result from the chordae tendineae (the chords) becoming stretched, and in some cases tearing. When a chord tears, the result is a leaflet that flails. Also, a normally structured valve may not function properly because of an enlargement of or shape change in the valve annulus. This condition is referred to as a dilation of the annulus and generally results from heart muscle failure. In addition, the valve may be defective at birth or because of an acquired disease.

Regardless of the cause (see Fig. 9), mitral valve dysfunction can occur when the leaflets do not coapt at peak contraction pressures. As Fig. 9 shows, the coaptation line of the two leaflets is not tight at ventricular systole. As a result, an undesired back flow of blood from the left ventricle into the left atrium can occur.

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Mitral regurgitation is a condition where, during contraction of the left ventricle, the mitral valve allows blood to flow backwards from the left ventricle into the left atrium. This has two important  
5 consequences.

First, blood flowing back into the atrium may cause high atrial pressure and reduce the flow of blood into the left atrium from the lungs. As blood backs up into the pulmonary system, fluid leaks into the lungs and  
10 causes pulmonary edema.

Second, the blood volume going to the atrium reduces volume of blood going forward into the aorta causing low cardiac output. Excess blood in the atrium over-fills the ventricle during each cardiac cycle and  
15 causes volume overload in the left ventricle.

Mitral regurgitation is measured on a numeric Grade scale of 1+ to 4+ by either contrast ventriculography or by echocardiographic Doppler assessment. Grade 1+ is trivial regurgitation and has  
20 little clinical significance. Grade 2+ shows a jet of reversed flow going halfway back into the left atrium. Grade 3 regurgitation shows filling of the left atrium with reversed flow up to the pulmonary veins and a contrast injection that clears in three heart beats or  
25 less. Grade 4 regurgitation has flow reversal into the pulmonary veins and a contrast injection that does not clear from the atrium in three or fewer heart beats.

Mitral regurgitation is categorized into two main types, (i) organic or structural and (ii)  
30 functional. Organic mitral regurgitation results from a structurally abnormal valve component that causes a valve leaflet to leak during systole. Functional mitral regurgitation results from annulus dilation due to primary congestive heart failure, which is itself  
35 generally surgically untreatable, and not due to a cause



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like severe irreversible ischemia or primary valvular heart disease.

Organic mitral regurgitation is seen when a disruption of the seal occurs at the free leading edge of the leaflet due to a ruptured chord or papillary muscle making the leaflet flail; or if the leaflet tissue is redundant, the valves may prolapse the level at which coaptation occurs higher into the atrium with further prolapse opening the valve higher in the atrium during ventricular systole.

Functional mitral regurgitation occurs as a result of dilation of heart and mitral annulus secondary to heart failure, most often as a result of coronary artery disease or idiopathic dilated cardiomyopathy. Comparing a healthy annulus in Fig. 7 to an unhealthy annulus in Fig. 9, the unhealthy annulus is dilated and, in particular, the anterior-to-posterior distance along the minor axis (line P-A) is increased. As a result, the shape and tension defined by the annulus becomes less oval (see Fig. 7) and more round (see Fig. 9). This condition is called dilation. When the annulus is dilated, the shape and tension conducive for coaptation at peak contraction pressures progressively deteriorate.

The fibrous mitral annulus is attached to the anterior mitral leaflet in one-third of its circumference. The muscular mitral annulus constitutes the remainder of the mitral annulus and is attached to by the posterior mitral leaflet. The anterior fibrous mitral annulus is intimate with the central fibrous body, the two ends of which are called the fibrous trigones. Just posterior to each fibrous trigone is the commissure of which there are two, the anterior medial (CM) and the posterior lateral commissure (CL). The commissure is where the anterior leaflet meets the posterior leaflet at the annulus.

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As before described, the central fibrous body is also intimate with the non-coronary leaflet of the aortic valve. The central fibrous body is fairly resistant to elongation during the process of mitral annulus dilation. It has been shown that the great majority of mitral annulus dilation occurs in the posterior two-thirds of the annulus known as the muscular annulus. One could deduce thereby that, as the annulus dilates, the percentage that is attached to the anterior mitral leaflet diminishes.

In functional mitral regurgitation, the dilated annulus causes the leaflets to separate at their coaptation points in all phases of the cardiac cycle. Onset of mitral regurgitation may be acute, or gradual and chronic in either organic or in functional mitral regurgitation.

In dilated cardiomyopathy of ischemic or of idiopathic origin, the mitral annulus can dilate to the point of causing functional mitral regurgitation. It does so in approximately twenty-five percent of patients with congestive heart failure evaluated in the resting state. If subjected to exercise, echocardiography shows the incidence of functional mitral regurgitation in these patients rises to over fifty percent.

Functional mitral regurgitation is a significantly aggravating problem for the dilated heart, as is reflected in the increased mortality of these patients compared to otherwise comparable patients without functional mitral regurgitation. One mechanism by which functional mitral regurgitation aggravates the situation in these patients is through increased volume overload imposed upon the ventricle. Due directly to the leak, there is increased work the heart is required to perform in each cardiac cycle to eject blood antegrade through the aortic valve and retrograde through the

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mitral valve. The latter is referred to as the regurgitant fraction of left ventricular ejection. This is added to the forward ejection fraction to yield the total ejection fraction. A normal heart has a forward  
5 ejection fraction of about 50 to 70 percent. With functional mitral regurgitation and dilated cardiomyopathy, the total ejection fraction is typically less than thirty percent. If the regurgitant fraction is half the total ejection fraction in the latter group the  
10 forward ejection fraction can be as low as fifteen percent.

### III. Prior Treatment Modalities

In the treatment of mitral valve regurgitation, diuretics and/or vasodilators can be used  
15 to help reduce the amount of blood flowing back into the left atrium. An intra-aortic balloon counterpulsation device is used if the condition is not stabilized with medications. For chronic or acute mitral valve regurgitation, surgery to repair or replace the mitral  
20 valve is often necessary.

Currently, patient selection criteria for mitral valve surgery are very selective. Possible patient selection criteria for mitral surgery include: normal ventricular function, general good health, a predicted  
25 lifespan of greater than 3 to 5 years, NYHA Class III or IV symptoms, and at least Grade 3 regurgitation. Younger patients with less severe symptoms may be indicated for early surgery if mitral repair is anticipated. The most common surgical mitral repair procedure is for organic  
30 mitral regurgitation due to a ruptured chord on the middle scallop of the posterior leaflet.

In conventional annuloplasty ring repair, the posterior mitral annulus is reduced along its circumference with sutures passed through a surgical  
35 annuloplasty sewing ring cuff. The goal of such a repair

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is to bring the posterior mitral leaflet forward toward to the anterior leaflet to better allow coaptation.

Surgical edge-to-edge juncture repairs, which can be performed endovascularly, are also made, in which  
5 a mid valve leaflet to mid valve leaflet suture or clip is applied to keep these points of the leaflet held together throughout the cardiac cycle. Other efforts have developed an endovascular suture and a clip to grasp and bond the two mitral leaflets in the beating heart.

10 Grade 3+ or 4+ organic mitral regurgitation may be repaired with such edge-to-edge technologies. This is because, in organic mitral regurgitation, the problem is not the annulus but in the central valve components.

However, functional mitral regurgitation can  
15 persist at a high level, even after edge-to-edge repair, particularly in cases of high Grade 3+ and 4+ functional mitral regurgitation. After surgery, the repaired valve may progress to high rates of functional mitral regurgitation over time.

20 In yet another emerging technology, the coronary sinus is mechanically deformed through endovascular means applied and contained to function solely within the coronary sinus.

It is reported that twenty-five percent of the  
25 six million Americans who will have congestive heart failure will have functional mitral regurgitation to some degree. This constitutes the 1.5 million people with functional mitral regurgitation. Of these, the idiopathic dilated cardiomyopathy accounts for 600,000 people. Of  
30 the remaining 900,000 people with ischemic disease, approximately half have functional mitral regurgitation due solely to dilated annulus.

By interrupting the cycle of progressive functional mitral regurgitation, it has been shown in  
35 surgical patients that survival is increased and in fact

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forward ejection fraction increases in many patients. The problem with surgical therapy is the significant insult it imposes on these chronically ill patients with high morbidity and mortality rates associated with surgical  
5 repair.

The need remains for simple, cost-effective, and less invasive devices, systems, and methods for treating dysfunction of a heart valve, e.g., in the treatment of organic and functional mitral valve  
10 regurgitation.

#### **Summary of the Invention**

The invention comprises devices, systems, and methods for reshaping a heart valve annulus. The invention has various aspects, including the placement  
15 and tensioning of implants within a heart chamber, the placement and tensioning of bridge implants within a heart chamber, the placement and manipulation of guide wires in conjunction with heart valve implants, and the use and manipulation of magnetic tools within the heart  
20 and elsewhere in the body.

For example, one aspect of the invention provides a system comprising an implant sized and configured for placement within a heart chamber. The system also includes a guide wire sized and configured  
25 for deployment in an intravascular path that extends from a first vascular access into the heart chamber and from the heart chamber to a second vascular access site, which can be the same as or different than the first access site. The guide wire has a first end extending beyond  
30 the first vascular access site and a second end extending beyond the second vascular access site. The system also includes a connector to connect an end of the implant to one end of the guide wire such that pulling on the other end of the guide wire pulls the implant along at least a  
35 portion of the intravascular path into the heart chamber.

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The implant can comprise a metallic material or polymer material or a metallic wire form structure or a polymer wire form structure or suture material or equine pericardium or porcine pericardium or bovine  
5 pericardium or preserved mammalian tissue.

For example, one aspect of the invention provides a system comprising a bridge element that is sized and configured to be implanted within the left atrium between the great cardiac vein and the interatrial  
10 septum. The bridge element has opposite ends. A guide wire is sized and configured to be deployed in an intravascular path that extends from a first vascular access site through an interatrial septum into the left atrium and from the left atrium through a great cardiac  
15 vein to a second vascular access site, which can be the same as or different than the first access site. The guide wire has a first end extending beyond the first vascular access site and a second end extending beyond the second vascular access site. A connector connects an  
20 end of the bridge element to one end of the guide wire such that pulling on the other end of the guide wire pulls the bridge element along at least a portion of the intravascular path into the left atrium. A posterior bridge stop is sized and configured to be secured to an  
25 end of the bridging element to abut against venous tissue within the great cardiac vein. An anterior bridge stop is sized and configured to be secured to the bridging element to abut against tissue on the interatrial septum within the right atrium. The posterior bridge stop and  
30 the anterior bridge stop can place the bridge element in tension between the interatrial septum and the great cardiac vein.

The guide wire can, e.g., extend along the intravascular path from the first vascular access site  
35 into a right atrium through a vena cava, from the right

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atrium through the interatrial septum into the left atrium, from the left atrium into and through a great cardiac vein into the right atrium, and from the right atrium through a vena cava to a second vascular access, which can be the same as or different than the first vascular access site.

The guide wire can, e.g., extend along the intravascular path from the first vascular access site into a right atrium through an IVC, from the right atrium through the interatrial septum into the left atrium, from the left atrium into and through a great cardiac vein into the right atrium, and from the right atrium through the SVC to a second vascular access site, which can be the same as or different than the first vascular access site.

The bridge element comprise, e.g., a metallic material or polymer material or a metallic wire form structure or a polymer wire form structure or suture material or equine pericardium or porcine pericardium or bovine pericardium or preserved mammalian tissue.

For example, one aspect of the invention provides an implant system comprising a first catheter and a second catheter. The first and second catheters each include a guide lumen having a distal opening. The system also includes a magnetic or ferromagnetic materials placed adjacent the distal openings of both guide lumens. The magnetic or ferromagnetic materials are sized and configured to magnetically couple the distal opening of the first catheter to the distal opening of the second catheter in an alignment that accommodates passage of an operative component between the guide lumens of the first and second catheters. The operative component can, e.g., comprise a guide wire or an implant structure.

For example, one aspect of the invention

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provides an implant system comprising a first catheter sized and configured to be deployed into a selected one of (a) a great cardiac vein through a coronary sinus and (b) a left atrium, and a second catheter sized and configured to be deployed into the other one of (a) the great cardiac vein through the coronary sinus and (b) the left atrium. The first and second catheters each include a guide lumen having a distal opening. The system also includes magnetic or ferromagnetic materials placed adjacent the distal openings of the guide lumens. The magnetic or ferromagnetic materials are magnetically attracted together to magnetically couple the distal opening of one catheter in the left atrium in alignment with the distal opening of another catheter in the great cardiac vein. The system also includes a tool sized and configured for passage through the guide lumen of a selected one of the first and second catheters. The tool includes a cutting element operative to penetrate tissue between the magnetically coupled distal openings. The tool includes a lumen accommodating passage of an operative component through the tool between the guide lumens of the first and second catheters. Alternatively, the tool can comprise a guide wire over which the operative element is passed.

For example, one aspect of the invention provides an implant system comprising a bridge sized and configured to span a left atrium between a great cardiac vein and an interatrial septum. A posterior bridge stop abuts venous tissue within the great cardiac vein. An anterior bridge stop abuts interatrial septum tissue in the right atrium. The bridge can comprise, e.g., a metallic material or polymer material or a metallic wire form structure or a polymer wire form structure or suture material or equine pericardium or porcine pericardium or bovine pericardium or preserved mammalian tissue. The



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bridge can be sized before or during implantation. At least one of the posterior bridge stop and the anterior bridge stop can be flexurally preshaped before implantation to conform to the shape of at least one of the tissue within the great cardiac vein and the interatrial septum tissue in the right atrium. At least one of the posterior bridge stop and the anterior bridge stop can be attached to the bridge prior to or during implantation. At least one of the posterior bridge stop and the anterior bridge stop can, e.g., be T-shaped.

For example, one aspect of the invention provides an implant system comprising a bridge implant sized and configured to span a left atrium between a great cardiac vein and an interatrial septum, a first catheter sized and configured to be deployed in the left atrium, a second catheter sized and configured to be deployed in the great cardiac vein adjacent a posterior mitral valve annulus in a desired alignment with a region of the first catheter in the left atrium. The system includes a tissue penetrating element sized and configured to be deployed, when the desired alignment exists, between the first and second catheters to create an access site between the left atrium and the great cardiac vein. The bridge implant is sized and configured to extend between the left atrium and the great cardiac vein through the access site.

The tissue penetrating element can be sized and configured, e.g., to be deployed from the first catheter from the left atrium into the great cardiac vein. Alternatively, the tissue penetrating element can be sized and configured, e.g., to be deployed from the second catheter from the great cardiac vein into the left atrium.

The first catheter can be sized and configured, e.g., to pass from the right atrium through

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the interatrial septum into the left atrium. The second catheter can be sized and configured, e.g., to pass from the right atrium through a coronary sinus into the great cardiac vein.

5           The bridge material can comprise, e.g., a metallic material or polymer material or a metallic wire form structure or a polymer wire form structure or suture material or equine pericardium or porcine pericardium or bovine pericardium or preserved mammalian tissue.

10           Other features and advantages of the invention shall be apparent based upon the accompanying description, drawings, and claims.

#### **Brief Description of the Drawings**

15           Fig. 1 is an anatomic anterior view of a human heart, with portions broken away and in section to view the interior heart chambers and adjacent structures.

20           Fig. 2 is an anatomic superior view of a section of the human heart showing the tricuspid valve in the right atrium, the mitral valve in the left atrium, and the aortic valve in between, with the tricuspid and mitral valves open and the aortic and pulmonary valves closed during ventricular diastole (ventricular filling) of the cardiac cycle.

25           Fig. 3 is an anatomic superior view of a section of the human heart shown in Fig. 2, with the tricuspid and mitral valves closed and the aortic and pulmonary valves opened during ventricular systole (ventricular emptying) of the cardiac cycle.

30           Fig. 4 is an anatomic anterior perspective view of the left and right atriums, with portions broken away and in section to show the interior of the heart chambers and associated structures, such as the fossa ovalis, coronary sinus, and the great cardiac vein.

35           Fig. 5 is an anatomic lateral view of a human heart with portions broken away and in section to show

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the interior of the left ventricle and associated muscle and chord structures coupled to the mitral valve.

Fig. 6 is an anatomic lateral view of a human heart with portions broken away and in section to show the interior of the left ventricle and left atrium and associated muscle and chord structures coupled to the mitral valve.

Fig. 7 is a superior view of a healthy mitral valve, with the leaflets closed and coapting at peak contraction pressures during ventricular systole.

Fig. 8 is an anatomic superior view of a section of the human heart, with the normal mitral valve shown in Fig. 7 closed during ventricular systole (ventricular emptying) of the cardiac cycle.

Fig. 9 is a superior view of a dysfunctional mitral valve, with the leaflets failing to coapt during peak contraction pressures during ventricular systole, leading to mitral regurgitation.

Figs. 10A and 10B are anatomic anterior perspective views of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes an inter-atrial bridging element that spans the mitral valve annulus, with a posterior bridge stop positioned in the great cardiac vein and an anterior bridge stop, including a septal member, positioned on the inter-atrial septum, the inter-atrial bridging element extending in an essentially straight path generally from a mid-region of the annulus to the inter-atrial septum.

Fig. 10C is an anatomic anterior perspective view of an alternative embodiment of the implant system shown in Figs. 10A and 10B, showing an anterior bridge stop without the addition of a septal member.

Fig. 11A is an anatomic anterior perspective view of the left and right atriums, with portions broken

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away and in section to show the presence of an implant system of the type shown in Figs. 10A and 10B, with the anterior region of the implant extending through a pass-through structure, such as a septal member, in the inter-atrial septum and situated in the superior vena cava.

Fig. 11B is an anatomic anterior perspective view of the left and right atriums, with portions broken away and in section to show the presence of an implant system of the type shown in Figs 10A and 10B, with the anterior region of the implant extending through a pass-through structure, such as a septal member, in the inter-atrial septum and situated in the inferior vena cava.

Fig. 11C is an anatomic anterior perspective view of the left and right atriums, with portions broken away and in section to show the presence of an implant system of the type shown in Figs. 10A to 10C, with the anterior region of the implant situated on the inter-atrial septum, as well as in the superior vena cava and the inferior vena cava.

Fig. 12 is an anatomic anterior perspective view of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes an inter-atrial bridging element that spans the mitral valve annulus, with a posterior region situated in the great cardiac vein and an anterior region situated on the interatrial septum, the inter-atrial bridging element extending in an essentially straight path generally from a lateral region of the annulus.

Fig. 13 is an anatomic anterior perspective view of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes an inter-atrial bridging element that spans the mitral valve annulus, with a posterior region situated in the great cardiac vein and an anterior

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region situated on the interatrial septum, the inter-atrial bridging element extending in an upwardly curved or domed path generally from a lateral region of the annulus.

5                   Fig. 14 is an anatomic anterior perspective view of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes an inter-atrial bridging element that spans the mitral valve annulus, with a posterior  
10 region situated in the great cardiac vein and an anterior region situated on the interatrial septum, the inter-atrial bridging element extending in a downwardly curved path generally from a lateral region of the annulus.

                  Fig. 15 is an anatomic anterior perspective  
15 view of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes an inter-atrial bridging element that spans the mitral valve annulus, with a posterior region situated in the great cardiac vein and an anterior  
20 region situated on the interatrial septum, the inter-atrial bridging element extending in a curvilinear path, bending around a trigone of the annulus generally from a mid-region region of the annulus.

                  Fig. 16 is an anatomic anterior perspective  
25 view of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes an inter-atrial bridging element that spans the mitral valve annulus, with a posterior region situated in the great cardiac vein and an anterior  
30 region situated on the interatrial septum, the inter-atrial bridging element extending in a curvilinear path, bending around a trigone of the annulus generally from a mid-region region of the annulus, as well as elevating in an arch toward the dome of the left atrium.

35                   Fig. 17 is an anatomic anterior perspective

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view of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes an inter-atrial bridging element that spans the mitral valve annulus, with a posterior region situated in the great cardiac vein and an anterior region situated on the interatrial septum, the inter-atrial bridging element extending in a curvilinear path, bending around a trigone of the annulus generally from a mid-region region of the annulus, as well as dipping downward toward the plane of the valve.

Fig. 18 is an anatomic anterior perspective view of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes two inter-atrial bridging elements that span the mitral valve annulus, each with a posterior bridge stop in the great cardiac vein and an anterior bridge stop on the inter-atrial septum, the inter-atrial bridging elements both extending in generally straight paths from different regions of the annulus.

Fig. 19 is an anatomic anterior perspective view of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes two inter-atrial bridging elements that span the mitral valve annulus, each with a posterior region situated in the great cardiac vein and an anterior region situated on the interatrial septum, the inter-atrial bridging elements both extending in generally curvilinear paths from adjacent regions of the annulus.

Fig. 20 is an anatomic anterior perspective view of the left and right atriums, with portions broken away and in section to show the presence of an implant system that includes three inter-atrial bridging elements that span the mitral valve annulus, each with a posterior region situated in the great cardiac vein and an anterior region situated on the interatrial septum, two of the

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inter-atrial bridging elements extending in generally straight paths from different regions of the annulus, and the third inter-atrial bridging elements extending in a generally curvilinear path toward a trigone of the annulus.

Fig. 21A is a side view of a septal member which may be used as part of the implant system of the type shown in Figs. 10A and 10B.

Fig. 21B is a side view of a deployed septal member of the type shown in Fig. 21A, showing the member sandwiching portions of the septum through an existing hole.

Figs. 22A and 22B are sectional views showing the ability of a bridge stop used in conjunction with the implant shown in Figs. 10A to 10C to move back and forth independent of the septal wall and inner wall of the great cardiac vein.

Figs. 23 to 30 are anatomic views depicting representative catheter-based devices and steps for implanting an implant system of the type shown in Figs. 10A to 10C.

Fig. 31 is an anatomic section view of the left atrium and associated mitral valve structure, showing mitral dysfunction.

Fig. 32 is an anatomic superior view of a section of the human heart, showing the presence of an implant system of the type shown in Figs. 10A and 10B.

Fig. 33 is an anatomic section view of the implant system taken generally along line 33-33 in Fig. 32, showing the presence of an implant system of the type shown in Figs. 10A and 10B, and showing proper coaptation of the mitral valve leaflets.

Figs. 34A to 34D are sectional views of a crimp tube for connecting a guide wire to a bridging element, and showing the variations in the crimps used.

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Fig. 35A is an anatomic partial view of a patient depicting access points used for implantation of an implant system, and also showing a loop guide wire accessible to the exterior the body at two locations.

5 Fig. 35B is an anatomic view depicting a representative alternative catheter-based device for implanting an implant system of the type shown in Figs. 10A to 10C, and showing a bridging element being pulled through the vasculature structure by a loop guide wire.

10 Fig. 36A is an anatomic partial view of a patient showing a bridge stop connected to a bridging element in preparation to be pulled and/or pushed through the vasculature structure and positioned within the great cardiac vein.

15 Fig. 36B is an anatomic view depicting a representative alternative catheter-based device for implanting a system of the type shown in Figs. 10A to 10C, and showing a bridge stop being positioned within the great cardiac vein.

20 Fig. 37A is a perspective view of a catheter used in the implantation of an implant system of the type shown in Figs. 10A to 10C.

Fig. 37B is a partial sectional view showing a magnetic head of the catheter as shown in Fig. 37A.

25 Fig. 38 is a perspective view of an additional catheter which may be used in the implantation of an implant system of the type shown in Figs. 10A to 10C.

30 Fig. 39 is a partial perspective view of the interaction between the magnetic head of the catheter shown in Fig. 37A and the magnetic head of the catheter shown in Fig. 38, showing a guide wire extending out of one magnetic head and into the other magnetic head.

35 Fig. 40 is an anatomic partial perspective view of the magnetic catheter heads shown in Fig. 39, with one catheter shown in the left atrium and one



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catheter shown in the great cardiac vein.

Fig. 41 is a perspective view of an additional catheter which may be used in the implantation of an implant system of the type shown in Figs. 10A to 10C.

5 Figs. 42A to 42E are partial perspective views of catheter tips which may be used with the catheter shown in Fig. 41.

Fig. 43A is a perspective view of a symmetrically shaped T-shaped bridge stop or member which  
10 may be used with the implant system of the type shown in Figs. 10A to 10C.

Fig. 43B is a perspective view of an alternative embodiment of the T-shaped bridge stop shown in Fig. 43A, showing the bridge stop being asymmetric and  
15 having one limb shorter than the other.

Fig. 44A is an exploded view of a bridge stop and associated driver which may be used with the implant system of the type shown in Figs. 10A to 10C.

Fig. 44B is a bottom view of the bridge stop  
20 shown in Fig. 44A.

Fig. 44C is a top view of a screw used in the bridge stop of the type shown in Fig. 44A.

Fig. 45A is an anatomic partial perspective view of alternative magnetic catheter heads, with one  
25 catheter shown in the left atrium and one catheter shown in the great cardiac vein, and showing a side to end configuration.

Fig. 45B is a partial sectional view of the alternative magnetic catheter heads of the type shown in  
30 Fig. 45A, showing a guide wire piercing the wall of the great cardiac vein and left atrium and extending into the receiving catheter.

Fig. 45C is a partial perspective view of an alternative magnetic head of the type shown in Fig. 45B.

35 Fig. 46 is an anatomic partial perspective

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view of an additional alternative embodiment for the magnetic catheter heads of the type shown in Fig. 45A, showing a side to side configuration.

5 Figs. 47A to 51 are perspective and sectional views of alternative embodiments of a bridge stop of the type shown in Fig. 44A.

10 Fig. 52A is a perspective view of an alternative embodiment of a T-shaped bridge stop or member of the type shown in Fig. 43A, showing a balloon expandable or self-expanding stent with a reinforcing strut.

15 Fig. 52B is a perspective view of an alternative embodiment of a T-shaped bridge stop or member of the type shown in Fig. 52A, showing the expandable or self-expanding stent in a lattice or half stent configuration.

Figs. 53A to 53F are perspective views showing alternative methods of connecting a bridging element to a bridge stop or T-shaped member.

20 Fig. 54 to 56A are perspective views of alternative implant systems of the type shown in Figs. 10A to 10C, showing alternative bridge locks in both the anterior bridge stop region and the posterior bridge stop region.

25 Fig. 56B is a side view of an alternative bridge stop of the type shown in Fig. 56A.

Fig. 57 to 59 are perspective views of additional alternative bridge locks.

30 Fig. 60A is a perspective view of an alternative bridge stop and showing the deployment catheter and deployment wire.

35 Fig. 60B is a side view of the alternative bridge stop of the type shown in Fig. 60A, showing the bridge stop in the deployment catheter prior to being deployed.

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Fig. 61A is a perspective view of an alternative bridge stop including a single layer of pericardium.

5 Fig. 61B is a side view of the alternative bridge stop of the type shown in Fig. 61A, showing the bridge stop in the deployment catheter prior to being deployed.

10 Fig. 62A is a perspective view of an alternative bridge stop including multiple layers of pericardium.

Fig. 62B is a side view of the alternative bridge stop of the type shown in Fig. 62A, showing the bridge stop in the deployment catheter prior to being deployed.

15 Fig. 63A is a perspective view of an alternative bridge stop including a balloon structure.

20 Fig. 63B is a side view of the alternative bridge stop of the type shown in Fig. 63A, showing the bridge stop in the deployment catheter prior to being deployed.

Fig. 63C is a side view of the alternative bridge stop of the type shown in Fig. 63A, showing the bridge stop just after exiting the deployment catheter and prior to being deployed.

25 Fig. 64 is an anatomic anterior perspective view of the left atrium and a portion of the right atrium, with portions broken away and in section to show the presence of an alternative implant system of the type shown in Figs. 10A to 10C, the alternative implant system  
30 includes a fixed length inter-atrial bridging element that spans the mitral valve annulus, with a posterior bridge stop positioned in the great cardiac vein and an anterior bridge stop positioned on the inter-atrial septum, the inter-atrial bridging element extending in an  
35 essentially straight path generally from a mid-region of

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the annulus to the inter-atrial septum.

Fig. 65 is an anatomic anterior perspective view of the left atrium, and a portion of the right atrium, with portions broken away and in section to show the presence of an alternative implant system of the type shown in Fig. 64, the alternative implant system includes a fixed length inter-atrial bridging element that spans the mitral valve annulus, with a posterior region situated in the great cardiac vein and an anterior region situated on the interatrial septum, the fixed length inter-atrial bridging element extending in a curvilinear path, bending around a trigone of the annulus generally from a mid-region region of the annulus, as well as dipping downward toward the plane of the valve.

Fig. 66 is an anatomic anterior perspective view of the left atrium, and a portion of the right atrium, with portions broken away and in section to show the presence of an alternative implant system of the type shown in Fig. 64, the alternative implant system includes a fixed length inter-atrial bridging element that spans the mitral valve annulus, with a posterior region situated in the great cardiac vein and an anterior region situated on the interatrial septum, the fixed length inter-atrial bridging element extending in a curvilinear path, bending around a trigone of the annulus generally from a mid-region region of the annulus, as well as elevating in an arch toward the dome of the left atrium.

Fig. 67 is a side view of a fixed length inter-atrial bridging element of the type shown in Fig. 64, and showing the fixed length bridging element with a connective head on a first end and a stop on a second end.

Fig. 68 is a side view of an arched or non-linear fixed length inter-atrial bridging element of the type shown in Figs. 65 and 66, and showing the arched

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fixed length bridging element with a connective head on a first end and a stop on a second end.

Fig. 69 is a perspective view of the arched fixed length inter-atrial bridging element of the type shown in Fig. 68, and showing and showing an alternative embodiment for a bridge stop on a second end.

Figs. 70A and 70B are perspective views showing the connective head of the fixed length bridging element guided by the tracking rail into the receiving aperture in a posterior or anterior bridge stop structure.

Figs. 71A and 71B are sectional views showing the ability of a bridge stop used in conjunction with the implant shown in Fig. 64 to move back and forth independent of the septal wall and inner wall of the great cardiac vein.

Fig. 72 is an anatomic anterior perspective view of the left atrium and a portion of the right atrium, with portions broken away and in section to show a step of implanting the implant system including the fixed length inter-atrial bridging element of the type shown in Fig. 64.

Fig. 73 is an anatomic anterior perspective view of the left atrium and a portion of the right atrium, with portions broken away and in section to show a step of implanting the implant system including the arched fixed length inter-atrial bridging element of the type shown in Figs. 65 and 66.

Figs. 74A and 74B are anatomic partial views of a patient depicting access points used for implantation of an implant system, and also showing a loop guide wire accessible to the exterior the body at a single location (femoral vein).

#### **Description of the Preferred Embodiment**

Although the disclosure hereof is detailed and

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exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention which may be embodied in other specific structures. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

**I. Trans-Septal Implants for Direct Shortening of the Minor Axis of a Heart Valve Annulus**

**A. Implant Structure**

Figs. 10A to 10C show embodiments of an implant 10 that is sized and configured to extend across the left atrium in generally an anterior-to-posterior direction, spanning the mitral valve annulus. The implant 10 comprises a spanning region or bridging element 12 having a posterior bridge stop region 14 and an anterior bridge stop region 16.

The posterior bridge stop region 14 is sized and configured to allow the bridging element 12 to be placed in a region of atrial tissue above the posterior mitral valve annulus. This region is preferred, because it generally presents more tissue mass for obtaining purchase of the posterior bridge stop region 14 than in a tissue region at or adjacent to the posterior mitral annulus. Engagement of tissue at this supra-annular location also may reduce risk of injury to the circumflex coronary artery. In a small percentage of cases, the circumflex coronary artery may pass over and medial to the great cardiac vein on the left atrial aspect of the great cardiac vein, coming to lie between the great cardiac vein and endocardium of the left atrium. However, since the forces in the posterior bridge stop region are directed upward and inward relative to the left atrium and not in a constricting manner along the long axis of the great cardiac vein, the likelihood of circumflex

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artery compression is less compared to other technologies in this field that do constrict the tissue of the great cardiac vein. Nevertheless, should a coronary angiography reveal circumflex artery stenosis, the symmetrically shaped posterior bridge stop may be replaced by an asymmetrically shaped bridge stop, such as where one limb of a T-shaped member is shorter than the other, thus avoiding compression of the crossing point of the circumflex artery. The asymmetric form may also be selected first based on a pre-placement angiogram.

An asymmetric posterior bridge stop may be utilized for other reasons as well. The asymmetric posterior bridge stop may be selected where a patient is found to have a severely stenotic distal great cardiac vein, where the asymmetric bridge stop better serves to avoid obstruction of that vessel. In addition, an asymmetric bridge stop may be chosen for its use in selecting application of forces differentially and preferentially on different points along the posterior mitral annulus to optimize treatment, i.e., in cases of malformed or asymmetrical mitral valves.

The anterior bridge stop region 16 is sized and configured to allow the bridging element 12 to be placed, upon passing into the right atrium through the septum, adjacent tissue in or near the right atrium. For example, as is shown in Figs. 10A to 10C, the anterior bridge stop region 16 may be adjacent or abutting a region of fibrous tissue in the interatrial septum. As shown, the bridge stop site 16 is desirably superior to the anterior mitral annulus at about the same elevation or higher than the elevation of the posterior bridge stop region 14. In the illustrated embodiment, the anterior bridge stop region 16 is adjacent to or near the inferior rim of the fossa ovalis. Alternatively, the anterior bridge stop region 16 can be located at a more superior

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position in the septum, e.g., at or near the superior rim of the fossa ovalis. The anterior bridge stop region 16 can also be located in a more superior or inferior position in the septum, away from the fossa ovalis, provided that the bridge stop site does not harm the tissue region.

Alternatively, as can be seen in Figs. 11A and 11B, the anterior bridge stop region 16, upon passing through the septum into the right atrium, may be positioned within or otherwise situated in the superior vena cava (SVC) or the inferior vena cava (IVC), instead of at the septum itself.

In use, the spanning region or bridging element 12 can be placed into tension between the two bridge stop regions 14 and 16. The implant 10 thereby serves to apply a direct mechanical force generally in a posterior to anterior direction across the left atrium. The direct mechanical force can serve to shorten the minor axis (line P-A in Fig. 7) of the annulus. In doing so, the implant 10 can also reactively reshape the annulus along its major axis (line CM-CL in Fig. 7) and/or reactively reshape other surrounding anatomic structures. It should be appreciated, however, the presence of the implant 10 can serve to stabilize tissue adjacent the heart valve annulus, without affecting the length of the minor or major axes.

It should also be appreciated that, when situated in other valve structures, the axes affected may not be the "major" and "minor" axes, due to the surrounding anatomy. In addition, in order to be therapeutic, the implant 10 may only need to reshape the annulus during a portion of the heart cycle, such as during late diastole and early systole when the heart is most full of blood at the onset of ventricular systolic contraction, when most of the mitral valve leakage



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occurs. For example, the implant 10 may be sized to restrict outward displacement of the annulus during late ventricular diastolic relaxation as the annulus dilates.

The mechanical force applied by the implant 10 across the left atrium can restore to the heart valve annulus and leaflets a more normal anatomic shape and tension. The more normal anatomic shape and tension are conducive to coaptation of the leaflets during late ventricular diastole and early ventricular systole, which, in turn, reduces mitral regurgitation.

In its most basic form, the implant 10 is made from a biocompatible metallic or polymer material, or a metallic or polymer material that is suitably coated, impregnated, or otherwise treated with a material to impart biocompatibility, or a combination of such materials. The material is also desirably radio-opaque or incorporates radio-opaque features to facilitate fluoroscopic visualization.

The implant 10 can be formed by bending, shaping, joining, machining, molding, or extrusion of a metallic or polymer wire form structure, which can have flexible or rigid, or inelastic or elastic mechanical properties, or combinations thereof. Alternatively, the implant 10 can be formed from metallic or polymer thread-like or suture material. Materials from which the implant 10 can be formed include, but are not limited to, stainless steel, Nitinol, titanium, silicone, plated metals, Elgiloy™, NP55, and NP57.

The implant 10 can take various shapes and have various cross-sectional geometries. The implant 10 can have, e.g., a generally curvilinear (i.e., round or oval) cross-section, or a generally rectilinear cross section (i.e., square or rectangular), or combinations thereof. Shapes that promote laminar flow and therefore reduce hemolysis are contemplated, with features such as

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smoother surfaces and longer and narrower leading and trailing edges in the direction of blood flow.

**B. The Posterior Bridge Stop Region**

5 The posterior bridge stop region 14 is sized and configured to be located within or at the left atrium at a supra-annular position, i.e., positioned within or near the left atrium wall above the posterior mitral annulus.

10 In the illustrated embodiment, the posterior bridge stop region 14 is shown to be located generally at the level of the great cardiac vein, which travels adjacent to and parallel to the majority of the posterior mitral valve annulus. This tributary of the coronary sinus can provide a strong and reliable fluoroscopic  
15 landmark when a radio-opaque device is placed within it or contrast dye is injected into it. As previously described, securing the bridging element 12 at this supra-annular location also lessens the risk of encroachment of and risk of injury to the circumflex  
20 coronary artery compared to procedures applied to the mitral annulus directly. Furthermore, the supra-annular position assures no contact with the valve leaflets therefore allowing for coaptation and reduces the risk of mechanical damage.

25 The great cardiac vein also provides a site where relatively thin, non-fibrous atrial tissue can be readily augmented and consolidated. To enhance hold or purchase of the posterior bridge stop region 14 in what is essentially non-fibrous heart tissue, and to improve  
30 distribution of the forces applied by the implant 10, the posterior bridge stop region 14 may include a posterior bridge stop 18 placed within the great cardiac vein and abutting venous tissue. This makes possible the securing of the posterior bridge stop region 14 in a non-fibrous  
35 portion of the heart in a manner that can nevertheless

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sustain appreciable hold or purchase on that tissue for a substantial period of time, without dehiscence, expressed in a clinically relevant timeframe.

**C. The Anterior Bridge Stop Region**

5           The anterior bridge stop region 16 is sized and configured to allow the bridging element 12 to remain firmly in position adjacent or near the fibrous tissue and the surrounding tissues in the right atrium side of the atrial septum. The fibrous tissue in this region  
10 provides superior mechanical strength and integrity compared with muscle and can better resist a device pulling through. The septum is the most fibrous tissue structure in its own extent in the heart. Surgically handled, it is usually one of the only heart tissues into  
15 which sutures actually can be placed and can be expected to hold without pledgets or deep grasps into muscle tissue, where the latter are required.

          As Figs. 10A to 10C show, the anterior bridge stop region 16 passes through the septal wall at a supra-  
20 annular location above the plane of the anterior mitral valve annulus. The supra-annular distance on the anterior side can be generally at or above the supra-annular distance on the posterior side. As before pointed out, the anterior bridge stop region 16 is shown in Figs. 10A  
25 to 10C at or near the inferior rim of the fossa ovalis, although other more inferior or more superior sites can be used within or outside the fossa ovalis, taking into account the need to prevent harm to the septal tissue and surrounding structures.

30           By locating the bridging element 12 at this supra-annular level within the right atrium, which is fully outside the left atrium and spaced well above the anterior mitral annulus, the implant 10 avoids the impracticalities of endovascular attachment at or  
35 adjacent to the anterior mitral annulus, where there is

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just a very thin rim of annulus tissue that is bounded anteriorly by the anterior leaflet, inferiorly by the aortic outflow tract, and medially by the atrioventricular node of the conduction system. The  
5 anterior mitral annulus is where the non-coronary leaflet of the aortic valve attaches to the mitral annulus through the central fibrous body. Anterior location of the implant 10 in the supra-annular level within the right atrium (either in the septum or in a vena cava)  
10 avoids encroachment of and risk of injury to both the aortic valve and the AV node.

The purchase of the anterior bridge stop region 16 in fibrous septal tissue is desirably enhanced by a septal member 30 or an anterior bridge stop 20, or a  
15 combination of both. Figs. 10A and 10B show the anterior bridge stop region including a septal member 30. Fig. 10C shows the anterior bridge stop region without a septal member. The septal member 30 may be an expandable device and also may be a commercially available device such as a  
20 septal occluder, e.g., Amplatzer® PFO Occluder (see Figs. 21A and 21B). The septal member 30 preferably mechanically amplifies the hold or purchase of the anterior bridge stop region 16 in the fibrous tissue site. The septal member 30 also desirably increases  
25 reliance, at least partly, on neighboring anatomic structures of the septum to make firm the position of the implant 10. In addition, the septal member 30 may also serve to plug or occlude the small aperture that was created in the fossa ovalis or surrounding area during  
30 the implantation procedure.

Anticipating that pinpoint pulling forces will be applied by the anterior bridge stop region 16 to the septum, the forces acting on the septal member 30 should be spread over a moderate area, without causing  
35 impingement on valve, vessels or conduction tissues. With

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the pulling or tensioning forces being transmitted down to the annulus, shortening of the minor axis is achieved. A flexurally stiff septal member is preferred because it will tend to cause less focal narrowing in the direction of bridge element tension of the left atrium as tension on the bridging element is increased. The septal member 30 should also have a low profile configuration and highly washable surfaces to diminish thrombus formation for devices deployed inside the heart. The septal member may also have a collapsed configuration and a deployed configuration. The septal member 30 may also include a hub 31 (see Figs. 21A and 21B) to allow attachment of the bridge stop 20. A septal brace may also be used in combination with the septal member 30 and anterior bridge stop 20 to distribute forces uniformly along the septum (see Fig. 11C). Alternatively, devices in the IVC or the SVC can be used as bridge stop sites (see Figs. 11A and 11B), instead of confined to the septum.

Location of the posterior and anterior bridge stop regions 14 and 16 having radio-opaque bridge locks and well demarcated fluoroscopic landmarks respectively at the supra-annular tissue sites just described, not only provides freedom from key vital structure damage or local impingement -- e.g., to the circumflex artery, AV node, and the left coronary and non-coronary cusps of the aortic valve - but the supra-annular focused sites are also not reliant on purchase between tissue and direct tension-loaded penetrating / biting / holding tissue attachment mechanisms. Instead, physical structures and force distribution mechanisms such as stents, T-shaped members, and septal members can be used, which better accommodate the attachment or abutment of mechanical levers and bridge locks, and through which potential tissue tearing forces can be better distributed. Further, the bridge stop sites 14, 16 do not require the operator

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to use complex imaging. Adjustment of implant position after or during implantation is also facilitated, free of these constraints. The bridge stop sites 14, 16 also make possible full intra-atrial retrieval of the implant 10 by  
5 endovascularly snaring and then cutting the bridging element 12 at either side of the left atrial wall, from which it emerges.

**D. Orientation of the Bridging Element**

In the embodiments shown in Figs. 10A to 10C,  
10 the implant 10 is shown to span the left atrium beginning at a posterior point of focus superior to the approximate mid-point of the mitral valve annulus, and proceeding in an anterior direction in a generally straight path directly to the region of anterior focus in the septum.  
15 As shown in Figs. 10A to 10C, the spanning region or bridging element 12 of the implant 10 may be preformed or otherwise configured to extend in this essentially straight path above the plane of the valve, without significant deviation in elevation toward or away from  
20 the plane of the annulus, other than as dictated by any difference in elevation between the posterior and anterior regions of placement.

Lateral or medial deviations and/or superior or inferior deviations in this path can be imparted, if  
25 desired, to affect the nature and direction of the force vector or vectors that the implant 10 applies. It should be appreciated that the spanning region or bridging element 12 can be preformed or otherwise configured with various medial/lateral and/or inferior/superior  
30 deviations to achieve targeted annulus and/or atrial structure remodeling, which takes into account the particular therapeutic needs and morphology of the patient. In addition, deviations in the path of the bridging element may also be imparted in order to avoid  
35 the high velocity blood path within a heart chamber, such

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as the left atrium.

For example, as shown in Fig. 12, the implant 10 is shown to span the left atrium beginning at a posterior region that is closer to a lateral trigone of the annulus (i.e., farther from the septum). Alternatively, the posterior region can be at a position that is closer to a medial trigone of the annulus (i.e., closer to the septum). From either one of these posterior regions, the implant 10 can extend in an anterior direction in a straight path directly to the anterior region in the septum. As shown in Fig. 12, like Fig. 10A, the spanning region or bridging element 12 of the implant 10 is preformed or otherwise configured to extend in an essentially straight path above the plane of the valve, without significant deviation in elevation toward or away from the plane of the annulus, other than as dictated by the difference in elevation, if any, between the posterior and anterior regions.

Regardless of the particular location of the posterior region (see Fig. 13), the spanning region or bridging element 12 of the implant 10 can be preformed or otherwise configured to arch upward above the plane of the valve toward the dome of the left atrium. Alternatively (see Fig. 14), the spanning region or bridging element 12 of the implant 10 can be preformed or otherwise configured to dip downward toward the plane of the valve toward the annulus, extending close to the plane of the valve, but otherwise avoiding interference with the valve leaflets. Or, still alternatively (see Fig. 15), the spanning region or bridging element 12 of the implant 10 can be preformed or otherwise configured to follow a curvilinear path, bending towards a trigone (medial or lateral) of the annulus before passage to the anterior region.

Various combinations of lateral/medial

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deviations and superior/inferior deviations of the spanning region or bridging element 12 of the implant 10 are of course possible. For example, as shown in Fig. 16, the spanning region or bridging element 12 can follow a curvilinear path bending around a trigone (medial or lateral) of the annulus as well as elevate in an arch away from the plane of the valve. Or, as shown in Fig. 17, the spanning region or bridging element 12 can follow a curvilinear path bending around a trigone (medial or lateral) of the annulus as well as dip toward the plane of the valve.

Regardless of the orientation, more than one implant 10 can be installed to form an implant system 22. For example, Fig. 18 shows a system 22 comprising a lateral implant 10L and a medial implant 10M of a type consistent with the implant 10 as described. Fig. 18 shows the implants 10L and 10M being located at a common anterior bridge stop region 16. It should be appreciated that the implants 10L and 10M can also include spaced apart anterior bridge stop regions.

One or both of the implants 10L and 10M can be straight (as in Fig. 12), or arch upward (as in Fig. 13), or bend downward (as in Fig. 14). A given system 10 can comprise lateral and medial implants 10L and 10M of different configurations. Also, a given system 22 can comprise more than two implants 10.

Fig. 19 shows a system 22 comprising two curvilinear implants 10L and 10M of the type shown in Fig. 15. In Fig. 19, the curvilinear implants 10L and 10M are shown to be situated at a common posterior region, but the implants 10 can proceed from spaced apart posterior regions, as well. One or both of the curvilinear implants 10L and 10M can be parallel with respect to the plane of the valve (as in Fig. 15), or arch upward (as in Fig. 16), or bend downward (as in Fig.



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17). A given system 22 can comprise curvilinear implants 10L and 10M of different configurations.

Fig. 20 shows a system 22 comprising a direct middle implant 10D, a medial curvilinear implant 10M, and  
5 a direct lateral implant 10L. One, two, or all of the implants 10 can be parallel to the valve, or arch upward, or bend downward, as previously described.

#### **E. Posterior and Anterior Bridge Stop**

It is to be appreciated that a bridge stop as  
10 described herein, including a posterior or anterior bridge stop, describes an apparatus that may releasibly hold the bridging element 12 in a tensioned state. As can be seen in Figs. 22A and 22B, bridge stops 20 and 18 respectively are shown releasibly secured to the bridging  
15 element 12, allowing the bridge stop structure to move back and forth independent of the inter-atrial septum and inner wall of the great cardiac vein during a portion of the cardiac cycle when the tension force may be reduced or becomes zero. Alternative embodiments are also  
20 described, all of which may provide this function. It is also to be appreciated that the general descriptions of posterior and anterior are non-limiting to the bridge stop function, i.e., a posterior bridge stop may be used anterior, and an anterior bridge stop may be used  
25 posterior.

When the bridge stop is in an abutting relationship to a septal member or a T-shaped member, for example, the bridge stop allows the bridging element to move freely within or around the septal member or T-  
30 shaped member, i.e., the bridging element is not connected to the septal member or T-shaped member. In this configuration, the bridging element is held in tension by the bridge stop, whereby the septal member or T-shaped member serves to distribute the force applied by  
35 the bridging element across a larger surface area.

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Alternatively, the bridge stop may be mechanically connected to the septal member or T-shaped member, e.g., when the bridge stop is positioned over and secured to the septal member hub. In this configuration, the bridging element is fixed relative to the septal member position and is not free to move about the septal member.

## II. General Methods of Trans-Septal Implantation

The implants 10 or implant systems 22 as just described lend themselves to implantation in a heart valve annulus in various ways. The implants 10 or implant systems 22 can be implanted, e.g., in an open heart surgical procedure. Alternatively, the implants 10 or implant systems 22 can be implanted using catheter-based technology via a peripheral venous access site, such as in the femoral or jugular vein (via the IVC or SVC) under image guidance, or trans-arterial retrograde approaches to the left atrium through the aorta from the femoral artery also under image guidance.

Alternatively, the implants 10 or implant systems 22 can be implanted using thoracoscopic means through the chest, or by means of other surgical access through the right atrium, also under image guidance. Image guidance includes but is not limited to fluoroscopy, ultrasound, magnetic resonance, computed tomography, or combinations thereof.

The implants 10 or implant systems 22 may comprise independent components that are assembled within the body to form an implant, or alternatively, independent components that are assembled exterior the body and implanted as a whole.

Figs. 23 to 30 show a representative embodiment of the deployment of an implant 10 of the type shown in Figs. 10A to 10C by a percutaneous, catheter-based procedure, under image guidance.

Percutaneous vascular access is achieved by

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conventional methods into the femoral or jugular vein, or a combination of both. As Figs. 23 and 24 show, under image guidance, a first catheter, or great cardiac vein catheter 40, and a second catheter, or left atrium catheter 60, are steered through the vasculature into the right atrium. It is a function of the great cardiac vein (GCV) catheter 40 and left atrium (LA) catheter 60 to establish the posterior bridge end stop region. Catheter access to the right and left atriums can be achieved through either a femoral vein to IVC or SVC route (in the latter case, for a caval brace) or an upper extremity or neck vein to SVC or IVC route (in the latter case, for a caval brace). In the case of the SVC, the easiest access is from the upper extremity or neck venous system; however, the IVC can also be accessed by passing through the SVC and right atrium. Similarly the easiest access to the IVC is through the femoral vein; however the SVC can also be accessed by passing through the IVC and right atrium. Figs. 23, 24, 27, 28 and 29 show access through both a SVC route and an IVC route for purposes of illustration.

The implantation of the implant 10 or implant systems 22 are first described here in four general steps. Each of these steps, and the various tools used, is then described with additional detail below in section III. Additionally, alternative implantation steps may be used and are described in section IV. Additional alternative embodiments of a bridge stop are described in section V, additional alternative embodiments of a T-shaped member or bridge stop are described in section VI, and additional alternative embodiments of an anterior bridge stop are described in section VII.

A first implantation step can be generally described as establishing the posterior bridge stop region 14. As can be seen in Fig. 24, the GCV catheter 40

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is steered through the vasculature into the right atrium. The GCV catheter 40 is then steered through the coronary sinus and into the great cardiac vein. The second catheter, or LA catheter 60, is also steered through the vasculature and into the right atrium. The LA catheter 60 then passes through the septal wall at or near the fossa ovalis and enters the left atrium. A Mullins<sup>TM</sup> catheter 26 may be provided to assist the guidance of the LA catheter 60 into the left atrium. Once the GCV catheter 40 and the LA catheter 60 are in their respective positions in the great cardiac vein and left atrium, it is a function of the GCV and LA catheters 40, 60 to configure the posterior bridge stop region 14.

A second step can be generally described as establishing the trans-septal bridging element 12. A deployment catheter 24 via the LA catheter 60 is used to position a posterior bridge stop 18 and a preferably preattached and predetermined length of bridging element 12 within the great cardiac vein (see Fig. 27). The predetermined length of bridging element 12, e.g., two meters, extends from the posterior bridge stop 18, through the left atrium, through the fossa ovalis, through the vasculature, and preferably remains accessible exterior the body. The predetermined length of bridging element may be cut or detached in a future step, leaving implanted the portion extending from the posterior bridge stop 18 to the anterior bridge stop 20. Alternatively, the bridging element 20 may not be cut or detached at the anterior bridge stop 20, but instead the bridging element 20 may be allowed to extend into the IVC for possible future retrieval.

A third step can be generally described as establishing the anterior bridge stop region 16 (see Fig. 29). The bridging element 12 is first threaded through the septal member 30. The septal member 30 is then

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advanced over the bridging element 12 in a collapsed condition through Mullins catheter 26, and is positioned and deployed at or near the fossa ovalis within the right atrium. A bridge stop 20 may be attached to the bridging  
5 element 12 and advanced with the septal member 30, or alternatively, the bridge stop 20 may be advanced to the right atrium side of the septal member 30 after the septal member has been positioned or deployed.

A fourth step can be generally described as  
10 adjusting the bridging element 12 for proper therapeutic effects. With the posterior bridge stop region 14, bridging element 12, and anterior bridge stop region 16 configured as previously described, a tension is placed on the bridging element 12. The implant 10 and associated  
15 regions may be allowed to settle for a predetermined amount of time, e.g., five or more seconds. The mitral valve and mitral valve regurgitation are observed for desired therapeutic effects. The tension on the bridging element 12 may be adjusted until a desired result is  
20 achieved. The bridge stop 20 is then allowed to secure the bridging element 12 when the desired tension or measured length or degree of mitral regurgitation reduction is achieved.

### **III. Detailed Methods and Implantation Apparatus**

25 The four generally described steps of implantation will now be described in greater detail, including the various tools and apparatus used in the implantation of the implant 10 or implant systems 22. An exemplary embodiment will describe the methods and tools  
30 for implanting an implant 10. These same or similar methods and tools may be used to implant an implant system 22 as well.

#### **A. Establish Posterior Bridge Stop Region**

##### **1. Implantation Tools**

35 Various tools may be used to establish the

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posterior bridge stop region 14. For example, the great cardiac vein (GCV) catheter 40, the left atrium (LA) catheter 60, and a cutting catheter 80 may be used.

Fig. 37A shows one embodiment of the GCV catheter 40 in accordance with the present invention. The GCV catheter 40 preferably includes a magnetic or ferromagnetic head 42 positioned on the distal end of the catheter shaft 45, and a hub 46 positioned on the proximal end. The catheter shaft 45 may include a first section 48 and a second section 50. The first section 48 may be generally stiff to allow for torquability of the shaft 45, and may be of a solid or braided construction. The first section 48 includes a predetermined length, e.g., fifty centimeters, to allow positioning of the shaft 45 within the vasculature structure. The second section 50 may be generally flexible to allow for steerability within the vasculature, i.e., into the coronary sinus. The second section 50 may also include a predetermined length, e.g., ten centimeters. The inner diameter or lumen 52 of the catheter shaft 45 is preferably sized to allow passage of a GCV guide wire 54, and additionally an LA guide wire 74 (see Figs. 39 and 40). Both the GCV guide wire 54 and the LA guide wire 74 may be pre-bent, and both may be steerable. The GCV catheter 40 preferably includes a radio-opaque marker 56 to facilitate adjusting the catheter under image guidance to align with the LA catheter 60.

The magnetic or ferromagnetic head 42 is preferably polarized to magnetically attract or couple the distal end of the LA catheter 60 (see Figs. 37B and 25). The head 42 includes a side hole 58 formed therein to allow for passage of the LA guide wire 74. As shown in Fig. 40, the left atrial side 43 of the head 42 has an attracting magnetic force, and the exterior of the heart side 44 of the head 42 has a repelling magnetic force. It

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should be appreciated that these magnetic forces may be reversed, as long as the magnetic forces in each catheter coincide with proper magnetic attraction. The magnetic head 42 preferably includes a bullet or coned shaped tip 55 to allow the catheter to track into the vasculature system. Within the tip 55 is an end hole 59, configured to allow for passage of the GCV guide wire 54.

Fig. 38 shows one embodiment of the LA catheter 60. Similar to the GCV catheter 40, the LA catheter 60 preferably includes a magnetic or ferromagnetic head 62 positioned on the distal end of the catheter shaft 65 and a hub 66 positioned on the proximal end. The catheter shaft 65 may include a first section 68 and a second section 70. The first section 68 may be generally stiff to allow for torquability of the shaft 65, and may be of a solid or braided construction. The first section 68 includes a predetermined length, e.g., ninety centimeters, to allow positioning of the shaft 65 within the vasculature structure. The second section 70 may be generally flexible and anatomically shaped to allow for steerability through the fossa ovalis and into the left atrium. The second section 70 may also include a predetermined length, e.g., ten centimeters. The inner diameter or lumen 72 of the catheter shaft 65 is preferably sized to allow passage of an LA guide wire 74, and additionally may accept the guide wire 54 passed from the GCV. The LA catheter 60 may include a radio-opaque marker 76 to facilitate adjusting the catheter 60 under image guidance to align with the GCV catheter 40.

The magnetic or ferromagnetic head 62 of the LA catheter 60 is polarized to magnetically attract or couple the distal end of the GCV catheter 40. As shown in Fig. 40, end side 64 of the head 62 is polarized to attract the GCV catheter head 42. The magnetic forces in the head 62 may be reversed, as long as attracting

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magnetic poles in the LA catheter 60 and the GCV catheter 40 are aligned. The magnetic head 62 preferably includes a generally planar tip 75, and also includes a center bore 78 sized for passage of the cutting catheter 80 and the LA guide wire 74 (see Fig. 38).

Fig. 41 shows the cutting catheter 80 preferably sized to be positioned within the inner diameter or lumen 72 of the LA catheter 60. Alternatively, the cutting catheter 80 may be positioned over the LA guide wire 74 with the LA catheter 60 removed.

The cutting catheter 80 preferably includes a hollow cutting tip 82 positioned on the distal end of the catheter shaft 85, and a hub 86 positioned on the proximal end. The catheter shaft 85 may include a first section 88 and a second section 90. The first section 88 may be generally stiff to allow for torquability of the shaft 85, and may be of a solid or braided construction. The first section 88 includes a predetermined length, e.g., ninety centimeters, to allow positioning of the shaft 85 within the vasculature structure and the LA catheter. The second section 90 may be generally flexible to allow for steerability through the fossa ovalis and into the left atrium. The second section 90 may also include a predetermined length, e.g., twenty centimeters. The inner diameter 92 of the catheter shaft 85 is preferably sized to allow passage of the LA guide wire 74. The cutting catheter 80 preferably includes a radio-opaque marker 96 positioned on the shaft 85 so as to mark the depth of cut against the radio-opaque magnet head 62 or marker 76 of the LA catheter 60.

The hollow cutting or penetrating tip 82 includes a sharpened distal end 98 and is preferably sized to fit through the LA catheter 60 and magnetic head 62 (see Fig. 42A). If desired, the cutting depth of the



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penetrating tip 82 may be controlled to avoid cutting or coring through the outer wall of the GCV into pericardial space. For example, as shown in Fig. 42B, the radio-opaque marker 96, which marks for visualization purposes the depth of the cut, may be covered with a polymeric coating 97, to increase its diameter. Alternatively, a thicker marker 96 can be used to increase its diameter. In this arrangement, as Fig. 42C shows, the bore 78 of the magnetic head 62 of the LA catheter 60 can include a step transition 79 from larger diameter to smaller diameter. Traversing the bore 78 of the magnetic head 62, the increased diameter of the coating 97 (or otherwise thicker marker 96), interferes with the step transition 79, impeding further passage of the penetrating tip 82 of cutting catheter 80 beyond the magnetic head 62 (as Fig. 42C shows). Other interfering stop mechanisms can be used. Typically, most GVC diameters range from 8 mm to 15 mm, and the distances to be cut or cored by the penetrating tip 82 from the LA to the GVC range from 1mm to 4 mm. This results in an acceptable excursion length of the penetrating tip 82 of cutting catheter 80 beyond the magnetic head 62 in a range of 5 mm to 8 mm.

Alternatively, as seen in Figs. 42D and 42E, cutting or penetrating tips 100 and 105 may be used in place of, or in combination with, the hollow cutting tip 82. The tri-blade 100 of Fig. 42D includes a sharp distal tip 101 and three cutting blades 102, although any number of blades may be used. The tri-blade 100 may be used to avoid producing cored tissue, which may be a product of the hollow cutting tip 82. The elimination of cored tissue helps to reduce the possibility of an embolic complication. The sharp tipped guide wire 105 shown in Fig. 42E may also be used. The sharp tip 106 is positioned on the end of a guide wire to pierce the wall of the left atrium and great cardiac vein.

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## 2. Implantation Methods

Access to the vascular system is commonly provided through the use of introducers known in the art. A 16F or less hemostasis introducer sheath (not shown),  
5 for example, may be first positioned in the superior vena cava (SVC), providing access for the GCV catheter 40. Alternatively, the introducer may be positioned in the subclavian vein. A second 16F or less introducer sheath (not shown) may then be positioned in the right femoral  
10 vein, providing access for the LA catheter 60. Access at both the SVC and the right femoral vein, for example, also allows the implantation methods to utilize a loop guide wire. For instance, in a procedure to be described later, a loop guide wire is generated by advancing the LA  
15 guide wire 74 through the vasculature until it exits the body and extends external the body at both the superior vena cava sheath and femoral sheath. The LA guide wire 74 may follow an intravascular path that extends at least from the superior vena cava sheath through the  
20 interatrial septum into the left atrium and from the left atrium through atrial tissue and through a great cardiac vein to the femoral sheath. The loop guide wire enables the physician to both push and pull devices into the vasculature during the implantation procedure (see Figs.  
25 35A and 36A).

An optional step may include the positioning of a catheter or catheters within the vascular system to provide baseline measurements. An AcuNav™ intracardiac echocardiography (ICE) catheter (not shown), or similar  
30 device, may be positioned via the right femoral artery or vein to provide measurements such as, by way of non-limiting examples, a baseline septal-lateral (S-L) separation distance measurement, atrial wall separation, and a mitral regurgitation measurement. Additionally, the  
35 ICE catheter may be used to evaluate aortic, tricuspid,

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and pulmonary valves, IVC, SVC, pulmonary veins, and left atrium access.

The GCV catheter is then deployed in the great cardiac vein adjacent a posterior annulus of the mitral valve. From the SVC, under image guidance, the .035 inch GCV guide wire 54, for example, is advanced into the coronary sinus and to the great cardiac vein. Optionally, an injection of contrast with an angiographic catheter may be made into the left main artery from the aorta and an image taken of the left coronary system to evaluate the position of vital coronary arterial structures. Additionally, an injection of contrast may be made to the great cardiac vein in order to provide an image and a measurement. If the great cardiac vein is too small, the great cardiac vein may be dilated with a 5 to 12 millimeter balloon, for example, to midway the posterior leaflet. The GCV catheter 40 is then advanced over the GCV guide wire 54 to a location in the great cardiac vein, for example near the center of the posterior leaflet or posterior mitral valve annulus (see Fig. 23). The desired position for the GCV catheter 40 may also be viewed as approximately 2 to 6 centimeters from the anterior intraventricular vein takeoff. Once the GCV catheter 40 is positioned, an injection may be made to confirm sufficient blood flow around the GCV catheter 40. If blood flow is low or non-existent, the GCV catheter 40 may be pulled back into the coronary sinus until needed.

The LA catheter 60 is then deployed in the left atrium. From the femoral vein, under image guidance, the .035 inch LA guide wire 74, for example, is advanced into the right atrium. A 7F Mullins™ dilator with a trans-septal needle is deployed into the right atrium (not shown). An injection is made within the right atrium to locate the fossa ovalis on the septal wall. The septal wall at the fossa ovalis is then punctured with the

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trans-septal needle and the guide wire 74 is advanced into the left atrium. The trans-septal needle is then removed and the dilator is advanced into the left atrium. An injection is made to confirm position relative to the left ventricle. The 7F Mullins system is removed and then replaced with a 12F or other appropriately sized Mullins system 26. The 12F Mullins system 26 is positioned within the right atrium and extends a short distance into the left atrium.

As seen in Fig. 24, the LA catheter 60 is next advanced over the LA guide wire 74 and positioned within the left atrium. If the GCV catheter 40 had been backed out to allow for blood flow, it is now advanced back into position. The GCV catheter 40 is then grossly rotated to magnetically align with the LA catheter 60. Referring now to Fig. 25, preferably under image guidance, the LA catheter 60 is advanced and rotated if necessary until the magnetically attractant head 62 of the LA catheter 60 magnetically attracts to the magnetically attractant head 42 of the GCV catheter 40. The left atrial wall and the great cardiac vein venous tissue separate the LA catheter 60 and the GCV catheter 40. The magnetic attachment is preferably confirmed via imaging from several viewing angles, if necessary.

Next, an access lumen 115 is created into the great cardiac vein (see Fig. 26). The cutting catheter 80 is first placed over the LA guide wire 74 inside of the LA catheter 60. The cutting catheter 80 and the LA guide wire 74 are advanced until resistance is felt against the wall of the left atrium. The LA guide wire 74 is slightly retracted, and while a forward pressure is applied to the cutting catheter 80, the cutting catheter 80 is rotated and/or pushed. Under image guidance, penetration of the cutting catheter 80 into the great cardiac vein is confirmed. The LA guide wire 74 is then advanced into the

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great cardiac vein and further into the GCV catheter 40 toward the coronary sinus, eventually exiting the body at the sheath in the neck. The LA catheter 60 and the GCV catheter 40 may now be removed. Both the LA guide wire 74 and the GCV guide wire 54 are now in position for the next step of establishing the trans-septal bridging element 12.

**B. Establish Trans-Septal Bridging Element**

Now that the posterior bridge stop region 14 has been established, the trans-septal bridging element 12 is positioned to extend from the posterior bridge stop region 14 in a posterior to anterior direction across the left atrium and to the anterior bridge stop region 16.

In this exemplary embodiment of the methods of implantation, the trans-septal bridging element 12 is implanted via a left atrium to GCV approach. In this approach, the GCV guide wire 54 is not utilized and may be removed. Alternatively, a GCV to left atrium approach is also described. In this approach, the GCV guide wire 54 is utilized. The alternative GCV to left atrium approach for establishing the trans-septal bridging element 12 will be described in detail in section IV.

The bridging element 12 may be composed of a suture material or suture equivalent known in the art. Common examples may include, but are not limited to, 1-0, 2-0, and 3-0 polyester suture, stainless steel braid (e.g., .022 inch diameter), and NiTi wire (e.g., .008 inch diameter). Alternatively, the bridging element 12 may be composed of biological tissue such as bovine, equine or porcine pericardium, or preserved mammalian tissue, preferably in a gluteraldehyde fixed condition. Alternatively the bridging element 12 may be encased by pericardium, or polyester fabric or equivalent.

A bridge stop, such as a T-shaped bridge stop 120 is preferably connected to the predetermined length

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of the bridging element 12. The bridging element 12 may be secured to the T-shaped bridge stop 120 through the use of a bridge stop 150 (see Fig. 44A), or may be connected to the T-shaped bridge stop 120 by securing means 121, such as tying, welding, or gluing, or any combination thereof. As seen in Figs. 43A and 43B, the T-shaped bridge stop 120 may be symmetrically shaped or asymmetrically shaped, may be curved or straight, and preferably includes a flexible tube 122 having a predetermined length, e.g., three to eight centimeters, and an inner diameter 124 sized to allow at least a guide wire to pass through. The tube 122 is preferably braided, but may be solid as well, and may also be coated with a polymer material. Each end 126 of the tube 122 preferably includes a radio-opaque marker 128 to aid in locating and positioning the T-shaped bridge stop 120. The tube 122 also preferably includes atraumatic ends 130 to protect the vessel walls. The T-shaped bridge stop 120 may be flexurally curved or preshaped so as to generally conform to the curved shape of the great cardiac vein or interatrial septum and be less traumatic to surrounding tissue. The overall shape of the T-shaped bridge stop 120 may be predetermined and based on a number of factors, including, but not limited to the length of the bridge stop, the material composition of the bridge stop, and the loading to be applied to the bridge stop.

A reinforcing center tube 132 may also be included with the T-shaped bridge stop 120. The reinforcing tube 132 may be positioned over the flexible tube 122, as shown, or, alternatively, may be positioned within the flexible tube 122. The reinforcing tube 132 is preferably solid, but may be braided as well, and may be shorter in length, e.g., one centimeter, than the flexible tube 122. The reinforcing center tube 132 adds stiffness to the T-shaped bridge stop 120 and aids in

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preventing egress of the T-shaped member 120 through the cored or pierced lumen 115 in the great cardiac vein and left atrium wall.

Alternative T-shaped members or bridge locks  
5 and means for connecting the bridging element 12 to the T-shaped bridge locks are described in section VI.

As can be seen in Fig. 27, the T-shaped bridge  
stop 120 (connected to the leading end of the bridging  
element 12) is first positioned onto or over the LA guide  
10 wire 74. The deployment catheter 24 is then positioned  
onto the LA guide wire 74 (which remains in position and  
extends into the great cardiac vein) and is used to push  
the T-shaped bridge stop 120 through the Mullins catheter  
26 and into the right atrium, and from the right atrium  
15 through the interatrial septum into the left atrium, and  
from the left atrium through atrial tissue into a region  
of the great cardiac vein adjacent the posterior mitral  
valve annulus. The LA guide wire 74 is then withdrawn  
proximal to the tip of the deployment catheter 24. The  
20 deployment catheter 24 and the guide wire 74 are then  
withdrawn just to the left atrium wall. The T-shaped  
bridge stop 120 and the attached bridging element 12  
remain within the great cardiac vein. The length of  
bridging element 12 extends from the posterior T-shaped  
25 bridge stop 120, through the left atrium, through the  
fossa ovalis, through the vasculature, and preferably the  
trailing end remains accessible exterior the body.  
Preferably under image guidance, the trailing end of the  
bridging element 12 is gently pulled, letting the T-  
30 shaped bridge stop 120 separate from the deployment  
catheter 24. Once separation is confirmed, again the  
bridging element 12 is gently pulled to position the T-  
shaped bridge stop 120 against the venous tissue within  
the region of the great cardiac vein and centered over  
35 the great cardiac vein access lumen 115. The deployment

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catheter 24 and the guide wire 74 may then be removed (see Fig. 28).

5 The trans-septal bridging element 12 is now in position and extends in a posterior to anterior direction from the posterior bridge stop region 14, across the left atrium, and to the anterior bridge stop region 16. The bridging element 12 preferably extends through the vasculature structure and extends exterior the body.

**C. Establish Anterior Bridge Stop Region**

10 Now that the trans-septal bridging element 12 is in position, the anterior bridge stop region 16 is next to be established.

15 In one embodiment, the proximal portion or trailing end of the bridging element 12 extending exterior the body is then threaded through or around an anterior bridge stop, such as the septal member 30. Preferably, the bridging element 12 is passed through the septal member 30 outside of the body nearest its center so that, when later deployed over the fossa ovalis, the  
20 bridging element 12 transmits its force to a central point on the septal member 30, thereby reducing twisting or rocking of the septal member. The septal member is advanced over the bridging element 12 in a collapsed configuration through the Mullins catheter 26, and is  
25 positioned within the right atrium and deployed at the fossa ovalis and in abutment with interatrial septum tissue. The bridging element 12 may then be held in tension by way of a bridge stop 20 (see Figs. 29 and 30). The anterior bridge stop 20 may be attached to or  
30 positioned over the bridging element 12 and advanced with the septal member 30, or alternatively, the bridge stop 20 may be advanced over the bridging element 12 to the right atrium side of the septal member 30 after the septal member has been positioned or deployed.  
35 Alternatively, the bridge stop 20 may also be positioned



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over the LA guide wire 74 and pushed by the deployment catheter 24 into the right atrium. Once in the right atrium, the bridge stop 20 may then be attached to or positioned over the bridging element 12, and the LA guide wire 74 and deployment catheter 24 may then be completely removed from the body.

Fig. 44A is an exploded view of one embodiment of a bridge stop in accordance with the present invention. The bridge stop 150 preferably includes a tube shaped base 152 and a screw 154. The base 152 includes a first side 156 and a second side 158, wherein use, the first side 156 is disposed toward the septal member 30, or optionally, the first side is disposed over the septal member hub 31, and the second side 158 is adapted to receive the screw 154. The base 152 includes an axially configured bore 160 formed therein having threads 162 beginning at the second side 158 and extending partially within a length of the base 152, although the bore 160 may be threaded throughout its entire length. The threaded bore 160 includes a predetermined inner diameter 164, sized so as to allow the base 152 to be installed over a guide wire, and optionally, positioned over the septal member hub 31. A first channel 166 and, optionally, a second channel 168 may be included within the bore 160 extending from the first side 156 to partially within the base 152 to provide for passage of the bridging element 12 within the bridge stop 150 (see Fig. 44B).

A male threaded portion 170 of screw 154 extends from the screw base 172 to approximately midway the length of the screw 154 and is sized to be threadably received within the bore 160 of the base 152. The screw head 174 preferably includes torquing means such as parallel surfaces 176. Surfaces 176 are provided to allow the screw 154 to be tightened and loosened within the

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base 152. Screw 154 also includes a bore 178 formed therein, sized so as to allow the screw 154 to be installed over a guide wire, and optionally, positioned over the septal member hub 31. A first channel 182 and, optionally, a second channel 184 may be included within the screw bore 178 extending partially within the screw 154, or alternatively, throughout the entire length of the screw 154 (see Fig. 44C). The base 152 and the screw 154 are aligned such that the channel provides for free passage of the bridging element 12 within the bridge stop 150.

In use, the screw 154 is first partially screwed into the base 152, allowing the channel 166, 168 in the base 152 to mate with the channel 182, 184 in the screw 154. The bridging element 12 is then extended through the entire length of the bridge stop 150, and is positioned within the channel formed within the base 152 and the screw 154. The bridging element 12 is then tensioned and the screw 154 is torqued into the base using a driver 186, such that the bridging element 12 is spooled within the bridge stop 150 or around the septal member hub 31, preferably one or more times. When the screw 154 is torqued into the base all the way, the screw compresses against the bridging element 12, preventing any relative motion of the bridging element. The bridging element 12 can no longer move freely within the bridge stop 150, fixing the position of the bridge stop 150 on the bridging element 12.

The driver 186 includes parallel surfaces 188, which are configured to extend over the screw head 174 in a mating relationship with parallel surfaces 176 on the screw head 174. The driver 186 also includes a bore 190 formed therein, sized so as to allow the driver 186 to be positioned over a guide wire.

The bridge stop 150, and alternative

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embodiments to be described later, have a predetermined size, e.g., eight millimeters by eight millimeters, allowing them to be positioned adjacent a septal member or a T-shaped member, for example. The bridge locks are also preferably made of stainless steel or other biocompatible metallic or polymer materials suitable for implantation.

Additional alternative bridge stop embodiments are described in section V.

10           **D.     Bridging Element Adjustment**

The anterior bridge stop 20 is preferably positioned in an abutting relationship to the septal member 30, or optionally may be positioned over the septal member hub 31. The bridge stop 20 serves to adjustably stop or hold the bridging element 12 in a tensioned state to achieve proper therapeutic effects.

With the posterior bridge stop region 14, bridging element 12, and anterior bridge stop region 16 configured as previously described, a tension may be applied to the bridging element 12, either external to the body at the proximal portion of the bridging element 12, or internally, including within the vasculature structure and the heart structure. After first putting tension on the bridging element 12, the implant 10 and associated regions may be allowed to settle for a predetermined amount of time, e.g., five seconds. The mitral valve and its associated mitral valve regurgitation are then observed for desired therapeutic effects. The tension on the bridging element 12 may be repeatably adjusted following these steps until a desired result is achieved. The bridge stop 20 is then allowed to secure the desired tension of the bridging element 12. The bridging element 12 may then be cut or detached at a predetermined distance away from the bridge stop 20, e.g., zero to three centimeters into the right atrium.

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The remaining length of bridging element 12 may then be removed from the vasculature structure.

Alternatively, the bridging element 12 may be allowed to extend into the IVC and into the femoral vein, possibly extending all the way to the femoral access point. Allowing the bridging element to extend into the IVC and into the femoral vein would allow for retrieval of the bridging element in the future, for example, if adjustment of the bridging element is necessary or desired.

The bridging element adjustment procedure as just described including the steps of placing a tension, waiting, observing, and readjusting if necessary is preferred over a procedure including adjusting while at the same time - or real-time - observing and adjusting, such as where a physician places a tension while at the same time observes a real-time ultrasound image and continues to adjust based on the real-time ultrasound image. The waiting step is beneficial because it allows for the heart and the implant to go through a quiescent period. This quiescent period allows the heart and implant to settle down and allows the tension forces and devices in the posterior and anterior bridge stop regions to begin to reach an equilibrium state. The desired results are better maintained when the heart and implant are allowed to settle prior to securing the tension compared to when the mitral valve is viewed and tension adjusted real-time with no settle time provided before securing the tension.

Fig. 31 shows an anatomical view of mitral valve dysfunction prior to the implantation of the implant 10. As can be seen, the two leaflets are not coapting, and as a result the undesirable back flow of blood from the left ventricle into the left atrium can occur. After the implant 10 has been implanted as just

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described, the implant 10 serves to shorten the minor axis of the annulus, thereby allowing the two leaflets to coapt and reducing the undesirable mitral regurgitation (see Figs. 32 and 33). As can be seen, the implant 10 is positioned within the heart, including the bridging element 12 that spans the mitral valve annulus, the anterior bridge stop 20 and septal member 30 on or near the fossa ovalis, and the posterior bridge stop 18 within the great cardiac vein.

#### 10 IV. Alternative Implantation Steps

The steps of implantation as previously described may be altered due to any number of reasons, such as age, health, and physical size of patient, and desired therapeutic effects. In one alternative embodiment, the posterior T-shaped bridge stop 120 (or alternative embodiments) is implanted via a GCV approach, instead of the left atrial approach as previously described. In an additional alternative embodiment, the coring procedure of the left atrial wall is replaced with a piercing procedure from the great cardiac vein to the left atrium.

##### A. GCV Approach

As previously described, penetration of the cutting catheter 80 into the great cardiac vein is confirmed under image guidance (see Fig. 26). Once penetration is confirmed, the LA guide wire 74 is advanced into the great cardiac vein and into the GCV catheter 40. The LA guide wire 74 is further advanced through the GCV catheter 40 until its end exits the body (preferably at the superior vena cava sheath). The LA catheter 60 and the GCV catheter 40 may now be removed. Both the LA guide wire 74 and the GCV guide wire 54 are now in position for the next step of establishing the trans-septal bridging element 12 (see Fig. 35A). At this point, an optional exchange catheter 28 may be advanced

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over the LA guide wire 74, starting at either end of the guide wire 74 and entering the body at either the femoral sheath or superior vena cava sheath, and advancing the exchange catheter 28 until it exits the body at the other end of the guide wire 74. The purpose of this exchange catheter is to facilitate passage of the LA guidewire 74 and bridging element 12, in a procedure to be described below, without cutting or injuring the vascular and heart tissues. In a preferred embodiment, the exchange catheter 28 is about .040 to .060 inch ID, about .070 to .090 inch OD, about 150 cm in length, has a lubricious ID surface, and has an atraumatic soft tip on at least one end so that it can be advanced through the vasculature without injuring tissues. It is to be appreciated that the ID, OD, and length may vary depending on the specific procedure to be performed.

In the GCV approach, the trans-septal bridging element 12 is implanted via a GCV to left atrium approach. A predetermined length, e.g., two meters, of bridging element 12 (having a leading end and a trailing end) is connected at the leading end to the tip of the LA guide wire 74 that had previously exited the body at the superior vena cava sheath and the femoral sheath. In this embodiment, the LA guide wire 74 serves as the loop guide wire, allowing the bridging element to be gently pulled or retracted into and through at least a portion of the vasculature structure and into a heart chamber. The vascular path of the bridging element may extend from the superior vena cava sheath through the coronary sinus into a region of the great cardiac vein adjacent the posterior mitral valve annulus, and from the great cardiac vein through atrial tissue into the left atrium, and from the left atrium into the right atrium through the interatrial septum, and from the right atrium to the femoral sheath.

As can be seen in Figs. 34A to 34D, a crimp

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tube or connector 800 may be used to connect the bridging element 12 to at least one end of the LA guide wire 74. Fig. 34A shows a crimp tube 800 preferably having an outer protective shell 802 and an inner tube 804. The  
5 outer protective shell 802 is preferably made of a polymeric material to provide atraumatic softness to the crimp tube, although other crimpable materials may be used. The inner tube 804 may be made of a ductile or malleable material such as a soft metal so as to allow a  
10 crimp to hold the bridging element 12 and guide wire 74 in place. The crimp tube ends 806 may be gently curved inward to aid in the movement of the crimp tube as the tube 800 moves through the vasculature. It is to be appreciated that the crimp tube may simply comprise a  
15 single tube made of a ductile or malleable material.

The bridging element 12 is positioned partially within the crimp tube 800. A force is applied with a pliers or similar crimping tool to create a first crimp 808 (see Fig. 34B). The end of the bridging element  
20 may include a knot, such as a single overhand knot, to aid in the retention of the bridging element 12 within the crimp tube. Next, the LA guide wire 74 is positioned partially within the crimp tube 800 opposite the bridging element 12. A force is again applied with a pliers or  
25 similar crimping tool to create a second crimp 810 (see Fig. 34C). Alternatively, both the bridging element 12 and the guide wire 74 may be placed within the crimp tube 800 at opposite ends and a single crimp 812 may be used to secure both the bridging element 12 and the guide wire  
30 74 within the crimp tube (see Fig. 34D). It is to be appreciated that the crimp tube 800 may be attached to the bridging element 12 or guide wire prior to the implantation procedure so as to eliminate the step of crimping the bridging element 12 within the crimp tube  
35 800 during the implantation procedure. The guide wire 74

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is now ready to be gently retracted. It can also be appreciated that apparatus that uses adhesives or alternatively pre-attached mechanisms that snap together may also be used for connecting bridge elements to guidewires.

As can be seen in Fig. 35B, the LA guide wire 74 is gently retracted, causing the bridging element 12 to follow through the vasculature structure. If the optional exchange catheter 28 is used (as shown in Figs. 35 A and 35B), the LA guidewire 74 retracts through the lumen of the exchange catheter 28 without injuring tissues. The LA guide wire 74 is completely removed from the body at the femoral vein sheath, leaving the bridging element 12 extending from exterior the body (preferably at the femoral sheath), through the vasculature structure, and again exiting at the superior vena cava sheath. The LA guide wire 74 may then be removed from the bridging element 12 by cutting or detaching the bridging element 12 at or near the crimp tube 800.

A posterior bridge stop, such as a T-shaped bridge stop 120 is preferably connected to the trailing end of bridging element 12 extending from the superior vena cava sheath. The T-shaped bridge stop 120 is then positioned onto or over the GCV guide wire 54. A deployment catheter 24 is then positioned onto or over the GCV guide wire 54 and is used to advance or push the T-shaped bridge stop 120 and bridging element 12 through the right atrium, through the coronary sinus, and into the great cardiac vein. If the optional exchange catheter 28 is used, the exchange catheter is gently retracted with the bridging element 12 or slightly ahead of it (see Figs. 36A and 36B). Optionally, the bridging element 12 may be pulled from the femoral vein region, either individually, or in combination with the deployment catheter 24, to advance the T-shaped bridge stop 120 and



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bridging element 12 into position in the great cardiac vein. The GCV guide wire 54 is then retracted letting the T-shaped bridge stop 120 separate from the GCV guide wire 54 and deployment catheter 24. Preferably under image  
5 guidance, and once separation is confirmed, the bridging element 12 is gently pulled to position the T-shaped bridge stop 120 in abutment against the venous tissue within the great cardiac vein and centered over the GCV access lumen 115. The deployment catheter 24 and optional  
10 exchange catheter 28 may then be removed.

The T-shaped bridge stop 120 and the attached bridging element 12 remain within the great cardiac vein. The length of bridging element 12 extends from the posterior T-shaped bridge stop 120, through the left  
15 atrium, through the fossa ovalis, through the vasculature, and preferably remains accessible exterior the body. The bridging element 12 is now ready for the next step of establishing the anterior bridge stop region 16, as previously described, and as shown in Figs. 28 to  
20 30.

#### **B. Piercing Procedure**

In this alternative embodiment, the procedure to core a lumen from the left atrium into the great cardiac vein is replaced with a procedure where a sharp-tipped guide wire within the great cardiac vein is used  
25 to create a passage from the great cardiac vein into the left atrium. Alternative embodiments for the magnetic head of both the GCV catheter 40 and the LA catheter 60 are preferably used for this procedure.

30 Figs. 45A and 45B show an end to side polarity embodiment for the GCV catheter magnetic head 200 and the LA catheter magnetic head 210. Alternatively, a side to side polarity may be used. The GCV catheter magnetic head 200 can maintain the same configuration for both the end  
35 to side polarity and the end to end polarity, while the

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LA catheter magnetic head 215 is shown essentially rotated ninety degrees for the side to side polarity embodiment (see Fig. 46).

As seen in Fig. 45B, the GCV catheter magnetic head 200 includes a dual lumen configuration. A navigation guide wire lumen 202 allows the GCV guide wire 54 to extend through the cone or bullet shaped end 204 of the head 200 in order to steer the GCV catheter 40 into position. A second radially curved side hole lumen 206 allows the sharp tipped guide wire 105 (or tri-blade 100, for example) to extend through the head 200 and directs the sharp tipped guide wire 105 into the LA catheter magnetic head 210. The LA catheter magnetic head 210 includes a funneled end 212 and a guide wire lumen 214 (see Fig. 45C). The funneled end 212 directs the sharp tipped guide wire 105 into the lumen 214 and into the LA catheter shaft 65.

Fig. 46 shows the alternative embodiment of the LA catheter magnetic head 215 used with the side to side polarity embodiment. The head 215 may have the same configuration as the GCV catheter magnetic head 42 shown in Figs. 39 and 40 and described in section III. The head 215 includes a navigation guide wire lumen 216 at the cone or bullet shaped end 218, and a side hole 220. The side hole 220 funnels the sharp tipped guide wire 105 (or tri-blade 100, for example), from the GCV catheter 40 to the LA catheter 60 and directs the guide wire 105 into the LA catheter shaft 65.

In use, both the GCV catheter 40 and the LA catheter 60 are advanced into the great cardiac vein and left atrium as previously described. The GCV catheter 40 and the LA catheter 60 each includes the alternative magnetically attractant head portions as just described. As best seen in Figs. 45A and 45B, a sharp-tipped guide wire 105 is advanced through the GCV catheter 40 to the

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internal wall of the great cardiac vein. The sharp-tipped guide wire 105 is further advanced until it punctures or pierces the wall of the great cardiac vein and the left atrium, and enters the funneled end 212 within the LA catheter head 210. The sharp-tipped guide wire 105 is advanced further until it exits the proximal end of the LA catheter 60. Both the GCV catheter 40 and the LA catheter 60 may now be removed, leaving the GCV guide wire 54 and the sharp-tipped guide wire 105 in place. The posterior T-shaped bridge stop 120 is now implanted via the GCV approach, as previously described, and as shown in Figs. 35A to 36B.

#### C. Single Site Access

Some clinicians may seek to avoid SVC access through a neck region for various reasons, e.g., the typical placement of fluoroscopic equipment near the upper torso, or working near the head of an awake patient. In this situation, the clinician may prefer access only through the groin (femoral vein).

As Figs. 74A and 74B show, the steps of implantation as previously described can readily accommodate accessing the heart for the septal/sinus shortening procedure using the groin area (femoral vein) only. As shown in Fig. 74A, the proximal end of a single guide wire 74 can be passed through the LA catheter 60, which gains access through the right femoral vein into the right atrium through the IVC, and from there into the left atrium through the septum. The guide wire 74 exits into the GVC catheter 40 in the GVC in the left atrium, for passage through the GVC catheter 40, which gains access through the left femoral vein into the right atrium through the IVC, and from there into the GVC through the coronary sinus. The distal end of the guide wire 74 therefore exits from the left femoral vein. In this arrangement, when access is achieved through a

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femoral vein, the GVC catheter 40 requires a greater length than when access is achieved through the neck. Further, the GCV catheter 40 desirably includes a more "cane-like" shape at its distal end to make a bend into  
5 the coronary sinus.

Alternatively, since the femoral vein is relatively large, it is possible to place both LA catheter 60 and GVC catheter 60 in a single large hemostasis sheath in one vein (left or right), thus avoid  
10 two access locations.

In like fashion, a single access point procedure from the neck can be used, which has an advantage of a shorter access distance for the LA catheter 60.

15 **V. Alternative Bridge Stop Embodiments**

Additional alternative embodiments of bridge stop devices may be used and are herein described. The bridge stop serves to secure the bridging element 12 at the posterior or anterior bridge stop region 14, 16, or  
20 both.

Figs. 47A and 47B are perspective views of an alternative embodiment of a bridge stop 300 in accordance with the present invention. The bridge stop 300 preferably includes a fixed upper body 302 and a movable  
25 lower body 304. Alternatively, the upper body 302 may be movable and the lower body 304 may be fixed. The upper body 302 and lower body 304 are positioned circumjacent a tubular shaped rivet 306. The upper body 302 and lower body 304 are preferably held in position by the rivet  
30 head 308 and a base plate 310. The rivet 306 and base plate 310 includes a predetermined inner diameter 312, sized so as to allow the bridge stop 300 to be installed over a guide wire. A spring, such as a spring washer 314, or also known in the mechanical art as a Belleville  
35 Spring, is positioned circumjacent the rivet 306 and

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between the rivet head 308 and the upper body 302, and applies an upward force on the lower body 304. The lower body 304 is movable between a bridge unlocked position (see Fig. 47A), and a bridge locked position (see Fig. 47B). In the bridge unlocked position, the lower body 304 and the upper body 302 are not in contacting communication, creating a groove 320 between the upper body 302 and lower body 304. In the bridge locked position, the axial force of the spring washer 314 urges the lower body 304 into contacting, or near contacting communication with the upper body 302, whereby the bridging element 12, which has been positioned within the groove 320, is locked in place by the axial force of the lower body 304 being applied to the upper body 302.

In use, the bridging element 12 is positioned within the groove 320 while the lower body 304 is maintained in the bridge unlocked position 316. The bridge stop 300 is positioned against the septal member 30 and the bridging element 12 is adjusted to proper tension. The lower body 304 is then allowed to move toward the upper body 302, thereby fixing the position of the bridge stop 300 on the bridging element 12.

Figs. 48A and 48B are perspective views of an alternative embodiment of the bridge stop 350 shown in Figs. 47A and 47B. The bridge stop 400 preferably includes an extension or tension spring 402 wherein at least one revolution of the spring coils 404 is in a contacting relationship while the spring 402 is in a natural or no-load position. When in a tensioned state, the at least one revolution of the spring coils 404 is in a non-contacting relationship. In use, an axial tension force is applied to the spring 402, allowing the spring coils 404 to separate (see Fig. 48A). While in the tensioned state, the bridging element 12 is positioned between and / or around at least one, and preferably

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multiple spring coils 404. The bridge stop 400 is positioned against the septal member 30 and the bridging element 12 is adjusted to proper tension. The tension force is then removed from the spring 402 and the spring 404 is allowed to return to its no-load state (see Fig. 48B). In the spring's no-load state, the coils 404 provide a tight fit against the bridging element 12, thereby fixing the position of the bridge stop 400 on the bridging element 12.

Fig. 48I shows an alternative embodiment of a bridge stop 1000. Fig. 48I shows the bridge stop 1000 in a closed and locked condition on a bridging element 12. Fig. 48L also shows the bridge stop 1000 in the closed and locked condition, for retaining tension on the bridging element 12.

As shown in Fig. 48I, the bridge stop 1000 includes first and second jaws 1002 and 1004 held together by spring coils 1006. The interior facing surfaces of the jaws 1002 and 1004 defined a passage 1014 between them, which accommodates the bridging element 12. When the spring coils 1006 are in a normal, uncompressed condition, as shown in Fig. 48I, the passage 1014 includes a pinching region 1008, which is defined by the abutment of a pinch arm 1010 on the jaw 1004 against a sloping pinch surface 1012 on the jaw 1002. The pinching region 1008 applies clamping friction to the bridge element 12, preventing relative slippage between the bridge stop 1000 and the bridge element 12. The bridge stop 1000 is in the closed and locked condition, in which the passage 1014 is closed at the pinching region 1018.

As shown in Fig. 48F, the jaws 1002 and 1004 can be moved axially relative to each other, in response to a pulling force on the jaw 1004, concurrent with the application of an opposing force to the jaw 1002. In response to these concurrently applied forces, the spring

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coils 1006 are compressed, and the pinch arm 1010 moves away from abutment with the sloping pinch surface 1012. The pinching region 1018, and thus the passage 1014, are opened. The bridge stop 1000 in an opened and unlocked condition. When in this opened and unlocked condition, the bridge element 12 can be threaded through the passage 1014, and the bridge stop 1000 can be advanced along the bridge element 12. When the concurrent forces are removed, the spring coils 1006 return to their normally uncompressed condition, moving the jaws 1002 and 1004. The pinch arm 1010 returns back into abutment against the sloping pinch surface 1012. The bridge stop 1000 is again in the closed and locked condition (as shown in Fig. 48I). The passage 1014 is closed at the pinching region 1018, and the pinching region 1008 again applies clamping friction to the bridge element 12.

Fig. 48C shows a bridge stop control device 1020 for operating the bridge stop 1000 between its closed and locked condition and its open and unlocked condition. The bridge stop control device 1020 includes a stationary handle portion 1022 and movable handle portion 1024, and an elongated catheter body 1034 that extends distally from the handle portion 1024.

The handle portions 1022 and 1024 can be moved together and apart, between an adjacent condition (shown in Figs. 48C and 48G) and an apart condition (shown in Fig. 48E). A spring 1030 normally biases the handle portions toward their adjacent condition (as Fig. 48 C).

A spring-biased detent mechanism is carried within the handle portion 1024, comprising a spring loaded ball 1026 that is received with a detent 1028 when the handle portions 1022 and 1024 are in their apart condition (as shown in Fig. 48E). The ball 1026 within the detent 1028 releasably locks the handle portions in their apart condition (as Fig. 48E shows). The frictional

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locking force between the ball 1026 and detent 1028 yields in response to an external manual force, upon which the spring 1030 brings the handle portions 1022 and 1024 back to their adjacent condition.

5           The bridge stop control device 1020 includes a control wire 1032 that passes through the handle portion and through the elongated catheter body 1034. A collet assembly 1036 on the handle portion 1022 serves, by rotation, to releasably clamp the control wire 1032. The  
10 control wire 1032 includes a screw connector 1038 on its distal end. The screw connector 1038 is sized and configured to threadably engage a receptacle 1040 on the jaw 1004 (as Figs. 48D and 48F show).

15           In use, the bridge stop 1000 is coupled to the distal end of the catheter body 1034, but screwing the screw connector 1038 into the jaw receptacle 1040, as shown in Figs. 48C and 48D. With the bridge stop 1000 in its closed and locked condition (as shown by Fig. 48D), the collet assembly 1036 is rotated to releasably hold  
20 tension on the control wire 1032.

          The handle portions 1022 and 1024 can then be moved into their apart condition (as shown in Figs. 48E and 48F). This applies concurrent force upon the jaws 1002 and 1004 of the bridge stop 1000, sliding the jaws  
25 apart and placing the bridge stop 1000 in its open and unlocked condition (as shown in Fig. 48F). The bridge element 12 can be threaded through the bridge stop 1000, as Fig. 48F, and passed through the catheter body 1034 through an aperture 1042 near the movable handle portion  
30 1024 (see Fig. 48E). In this condition (see Figs. 48J and 48K), the bridge stop control device 1020 can be manipulated to slide the bridge stop 1000 along the bridge element 12 to a desired location on the bridge element 12.

35           Once the desired degree of tension is placed



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on the bridge element 12 (by pulling on the bridge element 12 with the bridge stop 1000 unlocked and open), the bridge stop 1000 is placed in its closed and locked condition (see Fig. 48K), by rotating the collect  
5 assembly 1036 to free tension from the control wire 1032. The tension placed on the bridge element 12 is thereby retained. The handle portions 1022 and 1024 can also be returned to their adjacent position at this time.

As shown in Fig. 48L, the bridge stop control  
10 device 1020 is released from the bridge stop 1000 by rotating the control wire 1032. Rotation of the control wire 1032 unthreads the screw connector 1038 from the receptacle 1040 on the jaw 1004 (as is also shown in Figs. 48G; 48H; and 48I), allowing separation of the  
15 bridge stop control device 1020 from the bridge stop 1000.

Fig. 49 is a cross sectional view of an alternative embodiment of a bridge stop 450 in accordance with the present invention. The bridge stop 450  
20 preferably includes a plunger 452 within a tube 454. The tube 454 includes a plunger bore 456 extending partially through the length of the tube 454. The bore 456 then tapers inward at 460 creating a smaller bore 462. An internally threaded portion 466 of plunger bore 456  
25 extends from the first side 468 of the tube 454 to approximately midway between the first side 468 and the second side 470 of tube 454. Alternatively, the threaded portion 466 may be external on the tube 454. The plunger 452 is positioned within the plunger bore 456. The  
30 plunger 452 has a conical shaped head 472 and a shaft 474 extending from the base 476 of the conical shaped head 472. A torque screw 478, having a first side 480 and a second side 482, is threaded into bore 456. The first side 480 includes receiver means for a driver tool to  
35 rotate the torque screw 478, such as, but not limited to

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phillips, slotted, six lobe, or square. The second side 482 includes a pocket 484. A compression spring 486 having a first end 488 is positioned within the pocket 484, and a second end 490 of the compression spring 486 is positioned over the shaft 474 of the plunger 452.

An aperture 492 is disposed within the wall of the shaft 474 at a point above where the plunger bore 456 begins to taper inward. Bridging element 12 is shown disposed through the small bore 462 and through aperture 492.

In use, the torque screw 478 may be backed off to allow the plunger head 472 to move away from the tapered portion 460 of the plunger bore 456. Bridging element 12 is disposed within bore 462 and extends out of the tube 454 at aperture 492. The bridge stop 450 is then positioned against the septal member 30 and the bridging element 12 is adjusted to proper tension. The torque screw 478 is then torqued into the bore 456, causing the plunger head 472 to provide a tight fit against the bridging element 12, thereby fixing the position of the bridge stop 450 on the bridging element 12.

Fig. 50 is a cross sectional view of an additional alternative embodiment of a bridge stop 550 in accordance with the present invention. The bridge stop 550 preferably includes a base portion 552 having a first side 554 and a second side 556, a cap 558 threaded over the base portion 552, and a collet 560 positioned between the second side 556 of the base 552 and the cap 558. The collet 560 is seated on the second side 556 of the base 552. A bore 562 extends axially through the base 552, collet 560, and cap 558. In use, the cap 558 may be backed off to allow the bore 562 within the collet 560 to expand sufficiently to allow the bridging element 12 to slide freely through the bridge stop 550. The bridge stop 550 is then positioned against the septal member 30 and

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the bridging element 12 is adjusted to proper tension. The cap 558 is then tightened onto the base 552, which causes the bore 562 within the collet 560 to close down. The collet 560 provides a tight fit against the bridging  
5 element 12, thereby fixing the position of the bridge stop 550 on the bridging element 12. Collet 560 can be made of an elastomer or deformable type of material to make the pinching force more distributed and less traumatic to the bridging element 12.

10 Fig. 51 is a perspective view of an additional alternative embodiment of a bridge stop 650 in accordance with the present invention. The bridge stop 650 comprises a housing 652 having a lid 654. The bridge stop 650 may be tubular in shape, and may include an axially  
15 positioned lumen 656 extending therethru; the lumen 656 being sized to allow the bridge stop 650 to be positioned over a guide wire for implantation and optionally secured to hub 31 of the septal member 30. A second radially offset axial lumen 658 also extends through the bridge  
20 stop 650. The second lumen 658 allows for passage of the bridging element 12 through the bridge stop 650.

Positioned within the housing 652 is a spring band 660 and a spacer 662. The spring band 660 is generally circular in shape and has a fixed end 664 and a  
25 free end 666. The fixed end 664 includes a tab 668 positioned within a slot 670 in the lid 654 to prevent movement of the fixed end. The free end 666 includes an inclined angle 672 which allows for circumferential displacement when the inclined angle 672 is depressed.  
30 The spacer 662 is positioned adjacent the spring band 660, and keeps the spring band in alignment and free of buckling. As seen in Fig. 51, a screw 674 may be positioned in the lid 654, and when turned into the bridge stop 650, the screw 674 provides a force on the  
35 inclined angle 672. The free end 666 of the spring band

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660 is caused to rotate toward the fixed end 664, thereby pinching the bridging element 12 within the bridge stop 650 (between the fixed end 664 and the free end 666), and fixing the position of the bridge stop 650 on the  
5 bridging element 12.

It is to be appreciated that each embodiment of the bridge stop may be configured to have a bridge securing configuration in its static state, so as to require a positive actuation force necessary to allow the  
10 bridging element to move freely within or around the bridge stop. When a desirable tension in the bridge element is achieved, the actuation force is removed, thereby returning the bridge stop back to its static state and securing the bridge stop to the bridging  
15 element. Alternatively, the bridge stop may be configured to allow free movement of the bridging element 12 in its static state, thereby requiring a positive securing force to be maintained on the bridge stop necessary to secure the bridging element within the bridge stop.

20 Preferably, the bridge securing feature is unambiguous via tactile or fluoroscopic feedback. The securing function preferably may be locked and unlocked several times, thereby allowing the bridging element to be readjusted. The bridge stop material is also desirably  
25 radio-opaque or incorporates radio-opaque features to enable the bridge stop to be located with fluoroscopy.

#### **VI. Alternative T-Shaped Bridge Stop Embodiments**

Additional alternative embodiments of T-shaped bridge stop devices may be used and are herein described.  
30 The T-shaped bridge stop may serve to secure the bridging element 12 at the anterior bridge stop region 16, or the posterior bridge stop region 14, or both. It is to be appreciated that the alternative embodiments of the T-shaped bridge stop devices may be symmetrical as shown,  
35 or may also be asymmetrically shaped.

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Fig. 52A is a perspective view of an alternative embodiment of a T-shaped bridge stop 700 in accordance with the present invention. The T-shaped bridge stop 700 preferably includes an intravascular  
5 stent 702 and, optionally, a reinforcing strut 704. The stent 702 may be a balloon expandable or self expanding stent. As previously described, the T-shaped bridge stop 700 is preferably connected to a predetermined length of the bridging element 12. The bridging element 12 may be  
10 held within, on, or around the T-shaped bridge stop 700 through the use of any of the bridge locks as previously described, or may be connected to the T-shaped bridge stop 700 by way of tying, welding, or gluing, for example, or any combination.

Fig. 52B is a perspective view of an alternative embodiment of the T-shaped bridge stop 700 in accordance with the present invention. The alternative T-shaped bridge stop 701 preferably includes a lattice or half round intravascular stent 703 and, optionally, a  
20 reinforcing strut 704. The "C" shaped stent 703 may be a balloon expandable stent or self expanding stent. As previously described, the T-shaped bridge stop 701 is preferably connected to a predetermined length of the bridging element 12. The bridging element 12 may be held  
25 within, on, or around the T-shaped bridge stop 701 through the use of any of the bridge locks as previously described, or may be connected to the T-shaped bridge stop 701 by way of tying, welding, or gluing, for example, or any combination.

30 Figs. 53A to 53E show alternative methods of connecting the bridging element 12 to a T-shaped bridge stop 710. Fig. 53A shows a T-shaped member 710 where the bridging element 12 is wound around the T-shaped member 710. The bridging element 12 may be secured by adhesive  
35 712, knot, or a securing band placed over the bridging

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element 12, for example. Alternatively, the bridging element 12 may first be threaded through a lumen 714 extending through the T-shaped member 710 perpendicular the length of the T-shaped member. The bridging element 12 may then be wound around the T-shaped member, and secured by adhesive 712, securing band, or knot, for example.

Fig. 53B shows a T-shaped member 710 where the bridging element 12 is welded or forged to a plate 716. The plate 716 may then be embedded within the T-shaped member 710, or alternatively, secured to the T-shaped member 710 by gluing or welding, for example.

Figs. 53C and 53D show alternative embodiments where a ball and socket joint 718 connects the bridging element 12 to the T-shaped member 710. In Fig. 53C, the ball and socket joint 718 is located external to the T-shaped member 710. Alternatively, the ball and socket joint 718 may be positioned partially or completely within the T-shaped member 710, as seen in Fig. 53D. The bridging element 12 is secured to the socket 720, and the ball 722 is secured to the T-shaped member 710. The ball and socket joint 718 allows for free rotation of the bridging element 12 relative to the T-shaped member 710 or vice versa. The ball and socket joint 718 is preferably made of a micro-machined stainless steel, although other implantable materials may be used as well.

Fig. 53E shows an additional alternative embodiment of the T-shaped member 710 where the bridging element 12 is embedded in a polymeric substrate 724 of the T-shaped member 710. In this embodiment, the bridging element 12 preferably is a braided stainless steel micro-cable. The end 726 of the bridging element 12 is separated into an assortment of strands 728, which are then embedded in the polymeric substrate 724.

Fig. 53F shows a guide wire or bridging

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element style hinged T-shaped bridge stop embodiment 730 having a hinged leg 732. When in the expanded state, as shown in Fig. 53F, the hinged leg 732 forms one arm of a "T." The hinged leg 732 has a "C" shaped or concave profile, allowing the hinged leg 732 to lie over the guide wire or bridging element 12 while tracking to its final location. When the guide wire or bridging element 12 is gently retracted, the hinged leg 732 pivots away from the bridging element 12 forming the T-shaped bridge stop.

#### VII. Alternative Anterior Bridge Stop Embodiments

In place of, or in combination with the septal member 30 previously described, alternative embodiments of an anterior bridge stop may be used.

Fig. 54 shows an implant 10 having a T-shaped bridge stop 710 in the great cardiac vein and an anterior T-shaped bridge stop 750. The anterior T-shaped bridge stop 750 may be of a construction of any of the T-shaped bridge stop embodiments described. The T-shaped member 750 includes a lumen 752 extending through the T-shaped member 750 perpendicular to the length of the T-shaped member. The bridging element 12 may be secured by a free floating bridge stop as previously described.

Fig. 55 shows an implant 10 having a T-shaped bridge stop 710 in the great cardiac vein and an anterior lattice style bridge stop 760. The lattice 762 is positioned on the septal wall at or near the fossa ovalis. Optionally, the lattice 762 may include a reinforcement strut 764 to distribute the bridging element 12 tension forces over a greater area on the septal wall. The anterior lattice style bridge stop 760 may be packed in a deployment catheter with the bridging element 12 passing through its center. The lattice 762 is preferably self expanding and may be deployed by a plunger. The bridging element 12 may be secured by a free

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floating bridge stop as previously described.

Fig. 56A shows an implant 10 having a T-shaped bridge stop 710 in the great cardiac vein and an anterior star shaped bridge stop 770. The star 772 is positioned on the septal wall at or near the fossa ovalis. The star shaped bridge stop 770 may be packed in a deployment catheter with the bridging element 12 passing through its center. The star 772 is preferably self expanding and may be deployed by a plunger. When the star shaped bridge stop 770 is deployed, the center portion 774 stands proud of the septal wall to concentrate forces to the star points 776 (see Fig. 56B). The bridging element 12 may be secured by a free floating bridge stop as previously described.

Fig. 57 shows an additional embodiment of an anterior bridge stop 820. The bridge stop 820 includes at least two arms 822 extending radially from a generally central portion 824, and preferably includes more than two arms, as shown in Fig. 57. The bridge stop 820 is positioned on the septal wall at or near the fossa ovalis. The bridge stop 820 may be packed in a deployment catheter with the bridging element 12 passing through its center lumen 826. The bridge stop is preferably self expanding and may be deployed by a plunger after being folded into a catheter. The bridging element 12 may be secured by a free floating bridge stop as previously described or fixed in position.

Fig. 58 shows an additional embodiment of an anterior bridge stop 830. The bridge stop 830 again includes at least two arms 832, and preferably includes more than two. In this embodiment, each arm 832 is an independent member, and is free to move relative to the remaining arms. The bridge stop 830 is positioned on the septal wall at or near the fossa ovalis. The bridge stop 830 may be packed in a deployment catheter with the



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bridging element 12 passing through a lumen 836 in each arm; the lumen being located generally central along the longitudinal axis of each arm. The bridge stop is preferably self expanding and may be deployed by a plunger. The bridging element 12 may be secured by a free floating bridge stop as previously described or fixed in position.

Fig. 59 shows an additional embodiment of an anterior bridge stop 840. The bridge stop 840 includes at least one main trunk 842, and at least one arm 844 extending radially from the trunk 842, and preferably more than one arm, as shown in Fig. 59. The bridge stop 840 is positioned on the septal wall at or near the fossa ovalis. The bridge stop 840 may be packed in a deployment catheter with the bridging element 12 passing through a lumen 846; the lumen being located generally central along the longitudinal axis of the trunk 842. The bridge stop is preferably self expanding and may be deployed by a plunger. The bridging element 12 may be secured by a free floating bridge stop as previously described or fixed in position.

Fig. 60A shows an additional embodiment of an anterior bridge stop 850. The bridge stop 850 includes at least one arm 852 extending radially from a generally central portion 854, and preferably includes more than one arm, as shown in Fig. 60A. The bridge stop 850 is positioned on the septal wall at or near the fossa ovalis. The bridge stop 850 may be packed in a deployment catheter 24 with the bridging element 12 passing through its center lumen 856 (see Fig. 60B). The bridge stop 850 may be self expanding and may be deployed by a plunger, or alternatively may be deployed by applying tension on a deployment wire 858 and pushing on the plunger to expand the at least one arm 852. The forces of the deployment wire 858 and plunger cause the bridge stop 850 to be

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plastically deformed into its final shape. The bridging element 12 may be secured by a free floating bridge stop as previously described or fixed in position.

5 Figs. 61A to 62B show additional embodiments of an anterior bridge stop incorporating the use of porcine or equine pericardium to spread the tension forces of the bridging element 12, and also to provide a padding surface to the septal wall and to promote the bridge stop's ingrowth within the septal wall tissue.

10 As can be seen in Fig. 61A, a pad 862 of pericardium is positioned on the septal wall side of a bridge stop 860. The bridge stop 860 as shown includes a plurality of arms 864 extending radially from a generally central portion 866. The bridge stop 860, including the  
15 pericardium pad 862, is positioned on the septal wall at or near the fossa ovalis, with the pericardium pad 862 positioned between the septal wall and the bridge stop 860. The bridge stop 860 and pericardium pad 862 may be packed in a deployment catheter 24 with the bridging  
20 element 12 passing through both the bridge stop 860 and the pericardium pad 862 (see Fig. 61B). The bridge stop 860, including the pericardium pad 862, is preferably self expanding and may be deployed by a plunger. The bridging element 12 may be secured by a free floating  
25 bridge stop as previously described or fixed in position.

Fig. 62A shows an alternative embodiment of the bridge stop 860. Fig. 62A shows a bridge stop 870 positioned between at least two layers of pericardium 872. Pericardium 872 may be a single piece of pericardium  
30 having a butterfly cut to allow the bridge stop 870 to be positioned between the two layers, or the pericardium may include at least two separate pads, so as to allow the bridge stop 870 to be positioned between the at least two pads. The bridge stop 870 as shown includes a plurality  
35 of arms 874 extending radially from a generally central

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portion 876. The bridge stop 870, including the pericardium pad 872, is positioned on the septal wall at or near the fossa ovalis, with one layer of the pericardium pad 872 being positioned between the septal wall and the bridge stop 870, and the other layer of pericardium 872 exposed to the right atrium. The bridge stop 870 and pericardium pad 872 may be packed in a deployment catheter 24 with the bridging element 12 passing through both the bridge stop 870 and the pericardium pad 872 (see Fig. 62B). The bridge stop 870, including the pericardium pad 872, is preferably self expanding and may be deployed by a plunger. The bridging element 12 may be secured by a free floating bridge stop as previously described or fixed in position.

Both bridge stop embodiments 860 and 870 may include any of the self-expanding embodiments described herein, and as shown are non-limiting embodiments for incorporation with a pericardium pad or pads. It should also be appreciated that pads 862 and 872 may be composed of biological tissue other than pericardium and further may be lined with polyester fabric or equivalent to promote tissue in-growth.

Figs. 63A to 63C show an additional embodiment of an inflatable anterior bridge stop 880. The bridge stop 880 includes a balloon portion 882 and a central portion 884. The balloon portion 882 may take on any number of shapes, and is shown as a loop or ring. The central portion 884 may comprise a fabric or other implantable material to allow for tissue ingrowth. The balloon 882 may be inflated with a glue material in a liquid state, such as an epoxy glue, or other materials that will harden allowing the balloon to maintain its expanded configuration. The resulting pressure from the inflation process encourages the balloon portion 882 and the central portion 884 to expand to its deployed

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configuration. When the balloon inflation material has hardened, the hoop or ring shaped balloon spreads the tension force from the bridging element 12 and keeps the central fabric portion open and flat. The bridge stop 880 is positioned on the septal wall at or near the fossa ovalis. The bridge stop 880 may be packed in a deployment catheter 24 with the bridging element 12 passing through a lumen 886 in the central portion 884 (see Fig. 63B). The bridge stop is preferably self expanding and may be deployed by a plunger. Fig. 63C shows the bridge stop 880 just after exiting the deployment catheter 24 and prior to inflation of the balloon portion 882. The bridging element 12 may be secured by a free floating bridge stop as previously described or fixed in position.

**VIII. Fixed Length Bridging Element For Predetermined Tension Across a Heart Valve Annulus or For Predetermined Reduction in Septal-Lateral Length**

In order to achieve desired septal-lateral mitral valve dimension, the proper bridge length between the fossa ovalis and the GCV must be selected.

The septal-lateral mitral valve annulus length and the fossa ovalis to GCV length may be readily assessed using three dimensional echocardiography or magnetic resonance imaging, for example, either prior to or during the implantation procedure in order to properly size the fixed length bridging element prior to implantation.

Figs. 64 to 66 show embodiments of an implant system 910 having a fixed length bridging element. Implantation of the implant 910 having a fixed length bridging element is similar to the implantation of the implant 10 and adjustable bridging element 12 as previously described, except that the bridging element is of a fixed length and is not adjusted during or after implantation. The overall length of the fixed length

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bridging element may be chosen as a percentage, e.g., 125 to 150 percent, of the desired septal-lateral length. The length of the fixed length bridging element will always be greater than the desired septal-lateral length.

5           Normal septal-lateral distances measured in normal persons may be used as a basis for determining the proper therapeutic septal-lateral distances in persons being treated. Target therapeutic septal-lateral distance may, for example, be chosen as some percentage, e.g. 125  
10   percent, of septal-lateral distance in normal persons. The target septal-lateral distance must be sufficient to produce a therapeutic reduction in mitral regurgitation, but not over-stretch or tear tissues.

          The use of a fixed length bridging element may  
15   reduce the complexity of the implantation of the implant system 910 because adjustment of a bridging element is not required. The implant system may also reduce the overall length of time for the implantation procedure.

          The fixed length bridging element may be  
20   generally straight, as shown in Fig. 67, or may be generally arched or non-linear, as shown in Figs. 68 and 69. Figs. 65 and 66 show a sample of alternative deviations of the path of the arched fixed length bridging element 932, similar to those shown in Figs. 12  
25   to 20. Any single deviation or combinations of lateral or medial deviations and/or superior or inferior deviations in this path can be imparted, if desired, to affect the nature and direction of the force vector or vectors that the implant 910 applies. It should be appreciated that  
30   the fixed length bridging element can be preformed or otherwise configured with various medial/lateral and/or inferior/superior deviations to achieve targeted annulus and/or atrial structure remodeling, which takes into account the particular therapeutic needs and morphology  
35   of the patient. In addition, deviations in the path of

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the fixed length bridging element may also be imparted in order to avoid the high velocity blood path within a heart chamber, such as the left atrium. Also, stainless steel and Nitinol bridge elements may be used (as previously described and represented by Figs. 13 to 17 and 19) that have curved septal to lateral components that impart desired ranges of tension and length in combination.

**A. Fixed Length Bridging Element Structure**

The fixed length bridging element may be constructed of a generally rigid material, such as stainless steel, in order to provide a predetermined reduction in the septal-lateral length, while allowing a wider range of tension across the heart valve annulus. Alternatively, the fixed length bridging element may be constructed of a semi-flexible or springy material, such as Nitinol, in order to provide a predetermined narrow range of tension across a heart valve annulus, such as the mitral valve annulus. A semi-flexible or springy material also facilitates the implantation of the fixed length bridging element using a deployment catheter. Nitinol has favorable fatigue properties and is also non-thrombogenic.

As shown in Fig. 67, the fixed length bridging element 912 comprises a hollow tube 920 having a connective or retentive member or head 922 at a first end and a retainer or stop 924 at a second end. The inner diameter of the hollow tube 920 must be large enough to enclose bridging element 12. The head 922 is preferably cone or chevron shaped and may include at least one crevice or slit 926 sized to allow each portion of the head 922 to flex so that the head can be inserted into a receiving aperture 123 in a T-shaped member or bridge stop 120 and snap into place (see Figs. 70A and 70B). The stop 924 at the second end of the hollow tube 920 may be

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any practical shape (i.e. circular, square, triangle, or rod shaped) that offers sufficient surface area to abut the septal member 30 without allowing the stop 924 of the fixed length bridging element 912 to pass through the septal member. Alternatively, a septal member 30 may not be used and the stop 924 may abut the septal wall. Stop 924, for example, may incorporate any of the bridge stop embodiments described herein, and more particularly may incorporate any of the embodiments described in Figs. 54 to 63C.

As previously described in relation to the implant 10, the stop 924 and the bridge stop 120 remain free to move back and forth independent of the interatrial septum and the inner wall of the great cardiac vein during a portion of the cardiac cycle when the tension force may be reduced or becomes zero (see Figs. 71A and 71B).

Figs. 68 and 69 show an alternative embodiment of a fixed length bridging element. The arched fixed length bridging element 932 comprises a hollow tube 940 having a connective or retentive head 942 at a first end and a retainer or stop 944 at a second end. The head 942 is preferably cone or chevron shaped and may include at least one crevice or slit 946 sized to allow each portion of the head 942 to flex so that the head can be inserted into a receiving aperture 123 in a T-shaped member or bridge stop 120 and snap into place (see Figs. 70A and 70B). The stop 944 at the second end of the hollow tube 940 may be any practical shape (i.e. circular, square, triangle, or rod shaped) that offers sufficient surface area to abut the septal member 30 without allowing the stop 944 of the fixed length bridging element 932 to pass through the septal member 30. Alternatively, a septal member 30 may not be used and the stop 944 may abut the septal wall. Stop 944, for example, may incorporate any

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of the bridge stop embodiments described herein, and more particularly may incorporate any of the embodiments described in Figs. 54 to 63C.

As previously described in relation to the implant 10, the stop 944 and the bridge stop 120 remain free to move back and forth independent of the inter-atrial septum and the inner wall of the great cardiac vein during a portion of the cardiac cycle when the tension force may be reduced or becomes zero (see Figs. 71A and 71B).

**B. Detailed Methods For Fixed Length Bridging Element Implantation**

The steps of implantation and implantation apparatus as described in sections III(A) "Establish Posterior Bridge Stop Region" and III(B) "Establish Trans-Septal Bridging Element" are also used in conjunction with the implantation of the fixed length bridging element 912 and 932 and are therefore not repeated here. The remaining steps for implantation of the fixed length bridging element are described below. In addition, the bridging element 12 as described in these steps takes on an alternative purpose of serving as a "tracking rail" for delivery of the fixed length bridging element to its final implanted position.

**1. Establish Anterior Bridge Stop Region**

Now that the trans-septal bridging element or tracking rail 12 is in position, the anterior bridge stop region 16 is next to be established. In an alternative embodiment not incorporating a septal member 30, the step including the deployment of the septal member 30 may be skipped.

As seen in Fig. 29, the LA guide wire 74 is first backed out to at least the right atrium. In one embodiment incorporating a septal member 30, the proximal portion of the tracking rail 12 extending exterior the



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body is then threaded through or around the septal member 30. Preferably, the tracking rail 12 is passed through the septal member 30 outside of the body nearest its center so that when the fixed length bridging element 912 later passes over the tracking rail 12, the stop 924 of the fixed length bridging element 912 will also be centered and will transmit its force to a central point on the septal member 30, thereby reducing twisting or rocking of the septal member. The septal member is advanced over the tracking rail 12, through the vasculature, and is positioned within the right atrium and deployed at the fossa ovalis in a manner consistent with the manufacturer's instructions. At this point, tension may be applied under image guidance to establish the appropriate tension and/or length of bridging needed.

## 2. Fixed Length Bridging Element Positioning

With the posterior bridge stop region 14, tracking rail 12, and anterior bridge stop region 16 configured as described, the fixed length bridging element 912, 932 is next to be positioned. External the body, the fixed length bridging element 912, 932 is positioned over the tracking rail 12 having an end remaining external the body. With a tension maintained on the tracking rail 12, the deployment catheter 24 may then be used to gently push the fixed length bridging element 912, 932 through the vasculature and into the right atrium, following the path of the tracking rail 12. When a septal member 30 is used, additional pushing of the deployment catheter 24 allows the shaped head of the fixed length bridging element 912, 932 to pass through the interstices of the septal member 30 until the stop 924, 944 of the fixed length bridging element comes to rest on the septal member 30 and restricts further passage (see Fig. 72). When a septal member 30 is not used, the stop 924, 944 comes to rest on the septal wall

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and restricts further passage. Fig. 73 shows the deployment of the arched fixed length bridging element 932 without the use of a septal member, and prior to the deployment of the stop 944.

5           Still with continued tension maintained on the tracking rail 12, a compressive force is applied to the deployment catheter 24 causing the shaped head 922, 942 to continue to follow the path of the tracking rail 12 directly into the receiving aperture 123 in the T-shaped member 120. The shaped head 922, 942 snaps into place  
10           within the aperture 123 in the T-shaped member (see Figs. 70A and 70B). The tracking rail 12 may then be cut or detached, leaving a portion free to dangle or recoil within the tube 920, 940 of the fixed length bridging element, with the remainder removed along with the  
15           deployment catheter 24.

          Alternatively, the tracking rail 12 may be allowed to extend into the IVC and into the femoral vein, possibly extending all the way to the femoral access  
20           point. Allowing the tracking rail to extend into the IVC and into the femoral vein would allow for future retrieval of the tracking rail, which would provide for access to the fixed length implant.

          The foregoing is considered as illustrative  
25           only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred  
30           embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

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I/We Claim:

1. A system comprising  
an implant sized and configured for placement  
within a heart chamber,  
5 a guide wire sized and configured for  
deployment in an intravascular path that extends from a  
first vascular access into the heart chamber and from the  
heart chamber to a second vascular access site, the guide  
wire having a first end extending beyond the first  
10 vascular access site and a second end extending beyond  
the second vascular access site, and  
a connector to connect an end of the implant  
to one end of the guide wire such that pulling on the  
other end of the guide wire pulls the implant along at  
15 least a portion of the intravascular path into the heart  
chamber.
2. A system according to claim 1  
wherein the implant comprises a metallic  
material or polymer material or a metallic wire form  
20 structure or a polymer wire form structure or suture  
material or equine pericardium or porcine pericardium or  
bovine pericardium or preserved mammalian tissue.
3. A system according to claim 1  
wherein the first access site is different  
25 than the second access site.
4. A system comprising  
a bridge element sized and configured to be  
implanted within the left atrium between the great  
cardiac vein and the interatrial septum, the bridge  
30 element having opposite ends,  
a guide wire sized and configured to be  
deployed in an intravascular path that extends from a  
first vascular access site through an interatrial septum  
into the left atrium and from the left atrium through a  
35 great cardiac vein to a second vascular access site, the

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guide wire having a first end extending beyond the first vascular access site and a second end extending beyond the second vascular access site,

5 a connector to connect an end of the bridge element to one end of the guide wire such that pulling on the other end of the guide wire pulls the bridge element along at least a portion of the intravascular path into the left atrium,

10 a posterior bridge stop sized and configured to be secured to an end of the bridging element to abut against venous tissue within the great cardiac vein, and an anterior bridge stop sized and configured to be secured to the bridging element to abut against tissue on the interatrial septum within the right atrium.

15 5. A system according to claim 4 wherein the second access site is different than the first vascular access site.

6. A system according to claim 4 wherein the guide wire extends along the  
20 intravascular path from the first vascular access site into a right atrium through a vena cava, from the right atrium through the interatrial septum into the left atrium, from the left atrium into and through a great cardiac vein into the right atrium, and from the right  
25 atrium through a vena cava to a second vascular access site different than the first vascular access site.

7. A system according to claim 4 wherein the guide wire extends along the  
intravascular path from the first vascular access site  
30 into a right atrium through an IVC , from the right atrium through the interatrial septum into the left atrium, from the left atrium into and through a great cardiac vein into the right atrium, and from the right atrium through the SVC to a second vascular access site  
35 different than the first vascular access site.

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8. A system according to claim 4  
wherein the bridge element comprises a  
metallic material or polymer material or a metallic wire  
form structure or a polymer wire form structure or suture  
5 material or equine pericardium or porcine pericardium or  
bovine pericardium or preserved mammalian tissue.

9. A system according to claim 4  
wherein the posterior bridge stop and the  
anterior bridge stop place the bridge element in tension  
10 between the interatrial septum and the great cardiac  
vein.

10. An implant system comprising  
a first catheter,  
a second catheter,  
15 the first and second catheters each including  
a guide lumen having a distal opening, and  
magnetic or ferromagnetic materials placed  
adjacent the distal openings of both guide lumens, the  
magnetic or ferromagnetic materials being sized and  
20 configured to magnetically couple the distal opening of  
the first catheter to the distal opening of the second  
catheter in an alignment that accommodates passage of an  
operative component between the guide lumens of the first  
and second catheters.

25 11. A system according to claim 10  
wherein at least one of the first or second  
catheters includes an elongated shaft comprising a  
generally stiff region spaced from the distal opening and  
a generally flexible region adjacent the distal opening.

30 12. A system according to claim 10  
wherein the operative component comprises a  
first guide wire.

13. A system according to claim 10  
wherein the operative component comprises an  
35 implant structure.

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14. A system according to claim 10  
wherein at least one of the first or second  
catheters includes an elongated shaft having a distal  
end, and a head carried at the distal end in which the  
5 distal opening is formed, the head including the magnetic  
or ferromagnetic material.

15. A system according to claim 14  
wherein the head includes opposite first and  
second side surfaces,  
10 wherein the distal opening is formed on the  
first side surface of the head, and  
wherein the magnetic or ferromagnetic material  
is also located on the first side surface of the head  
adjacent the distal opening.

15 16. A system according to claim 15  
wherein the opposite second side surface of  
the head includes a material that is not magnetically  
attracted to the magnetic or ferromagnetic material on  
the first side surface of the head.

20 17. A system according to claim 15  
wherein the magnetic or ferromagnetic material  
on the first side surface of the head includes a magnetic  
material having a polarity, and  
wherein the opposite second side surface of  
25 the head includes a magnetic material having a magnetic  
polarity opposite to the polarity of the magnetic  
material on the first side surface of the head.

18. A system according to claim 12  
wherein at least one of the first or second  
30 catheters accommodates passage of a second guide wire  
independent of the first-defined guide wire.

19. An implant system comprising  
a first catheter sized and configured to be  
deployed into a selected one of (a) a great cardiac vein  
35 through a coronary sinus and (b) a left atrium,

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a second catheter sized and configured to be deployed into the other one of (a) the great cardiac vein through the coronary sinus and (b) the left atrium,

the first and second catheters each including  
5 a guide lumen having a distal opening,

magnetic or ferromagnetic materials placed adjacent the distal openings of the guide lumens, the magnetic or ferromagnetic materials being magnetically attracted together to magnetically couple the distal  
10 opening of one catheter in the left atrium in alignment with the distal opening of another catheter in the great cardiac vein, and

a tool sized and configured for passage through the guide lumen of a selected one of the first  
15 and second catheters, the tool including a cutting element operative to penetrate tissue between the magnetically coupled distal openings, the tool including a lumen accommodating passage of an operative component through the tool between the guide lumens of the first  
20 and second catheters.

20. An implant system comprising

a first catheter sized and configured to be deployed into a selected one of (a) a great cardiac vein through a coronary sinus and (b) a left atrium,

25 a second catheter sized and configured to be deployed into the other one of (a) the great cardiac vein through the coronary sinus and (b) the left atrium,

the first and second catheters each including a guide lumen having a distal opening,

30 magnetic or ferromagnetic materials placed adjacent the distal openings of guide lumens, the magnetic or ferromagnetic materials being magnetically attracted together to magnetically couple the distal opening of one catheter in the left atrium in alignment  
35 with the distal opening of another catheter in the great

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cardiac vein, and

a guide wire sized and configured for passage through the guide lumen of a selected one of the first and second catheters, the guide wire including a distal element operative to penetrate tissue between the magnetically coupled distal openings to pass the guide wire between the guide lumens of the first and second catheters.

21. An implant system comprising  
a bridge sized and configured to span a left atrium between a great cardiac vein and an interatrial septum,

a posterior bridge stop that abuts venous tissue within the great cardiac vein, and  
an anterior bridge stop that abuts interatrial septum tissue in the right atrium.

22. An implant system according to claim 21 wherein the bridge comprises a metallic material or polymer material or a metallic wire form structure or a polymer wire form structure or suture material or equine pericardium or porcine pericardium or bovine pericardium or preserved mammalian tissue.

23. An implant system according to claim 21 wherein the bridge is sized before implantation.

24. An implant system according to claim 23 wherein the bridge comprises a hollow tube having a first end and a second end, the first end including a first retentive member and the second end including a second retentive member.

25. An implant system according to claim 21 wherein the bridge is sized during implantation.

26. An implant system according to claim 21 wherein at least one of the posterior bridge



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stop and the anterior bridge stop is symmetrical.

27. An implant system according to claim 21 wherein at least one of the posterior bridge stop and the anterior bridge stop is asymmetrical.

5 28. An implant system according to claim 21 wherein at least one of the posterior bridge stop and the anterior bridge stop is flexurally preshaped before implantation to conform to the shape of at least one of the tissue within the great cardiac vein and the  
10 interatrial septum tissue in the right atrium.

29. An implant system according to claim 21 wherein at least one of the posterior bridge stop and the anterior bridge stop is attached to the bridge prior to implantation.

15 30. An implant system according to claim 21 wherein at least one of the posterior bridge stop and the anterior bridge stop is attached to the bridge during implantation.

31. An implant system according to claim 21 wherein at least one of the posterior bridge stop and the anterior bridge stop is T-shaped.

20 32. An implant system according to claim 21 further including a member that mechanically amplifies purchase of at least one of the posterior and  
25 anterior bridge stop in abutting tissue.

33. An implant system comprising  
a bridge implant sized and configured to span  
a left atrium between a great cardiac vein and an  
interatrial septum,  
30 a first catheter sized and configured to be deployed in the left atrium,  
a second catheter sized and configured to be deployed in the great cardiac vein adjacent a posterior mitral valve annulus in a desired alignment with a region  
35 of the first catheter in the left atrium, and

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5 a tissue penetrating element sized and configured to be deployed, when the desired alignment exists, between the first and second catheters to create an access site between the left atrium and the great cardiac vein,

the bridge implant being sized and configured to extend between the left atrium and the great cardiac vein through the access site.

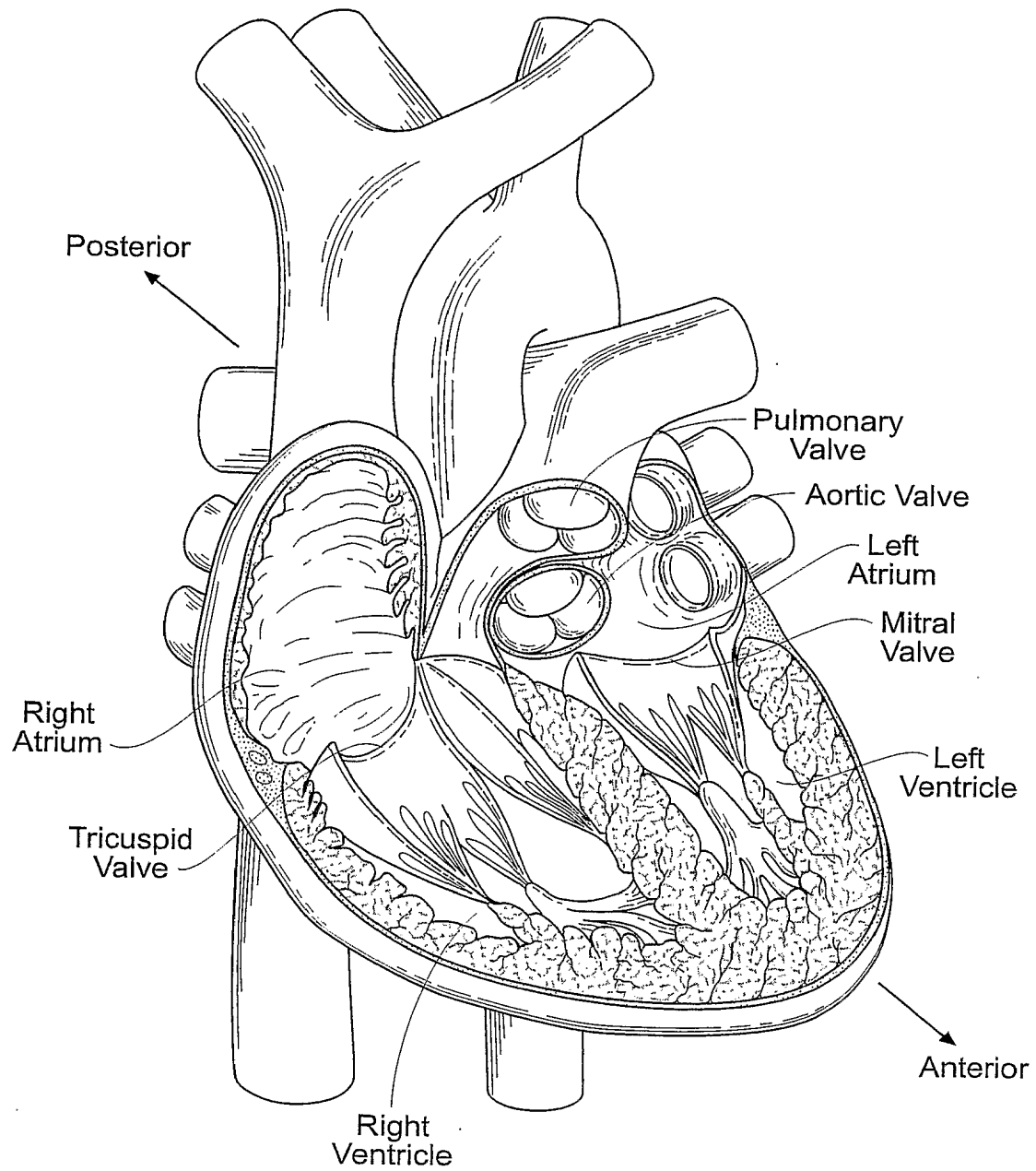
10 34. An implant system according to claim 33 wherein the tissue penetrating element is sized and configured to be deployed from the first catheter from the left atrium into the great cardiac vein.

15 35. An implant system according to claim 33 wherein the tissue penetrating element is sized and configured to be deployed from the second catheter from the great cardiac vein into the left atrium.

20 36. An implant system according to claim 33 wherein the first catheter is sized and configured to pass from the right atrium through the interatrial septum into the left atrium.

25 37. An implant system according to claim 33 wherein the second catheter is sized and configured to pass from the right atrium through a coronary sinus into the great cardiac vein.

30 38. An implant system according to claim 33 wherein the bridge material comprises a metallic material or polymer material or a metallic wire form structure or a polymer wire form structure or suture material or equine pericardium or porcine pericardium or bovine pericardium or preserved mammalian tissue.

*Fig. 1*

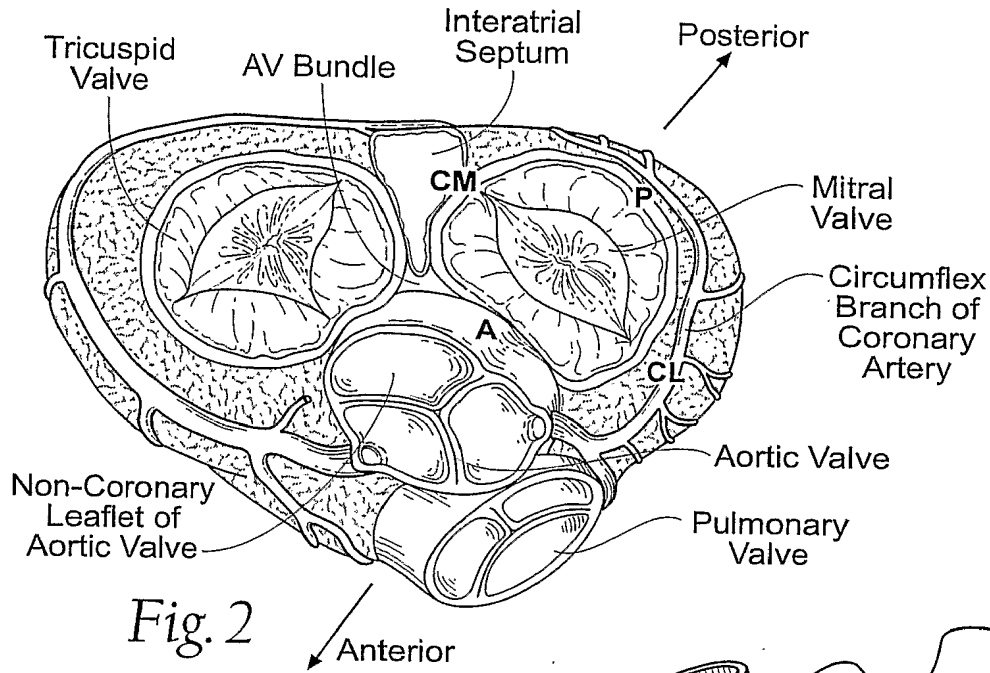


Fig. 2

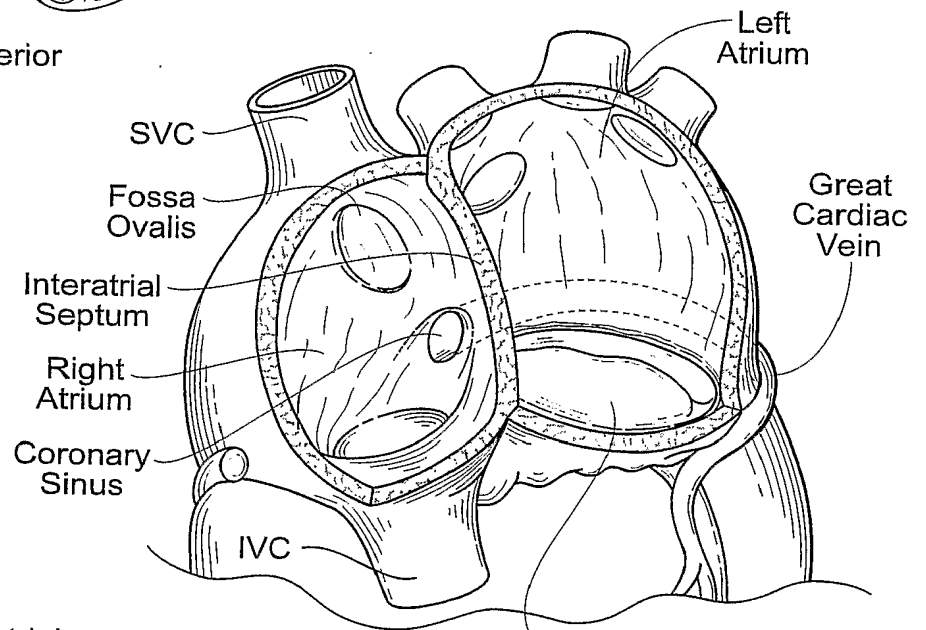


Fig. 3

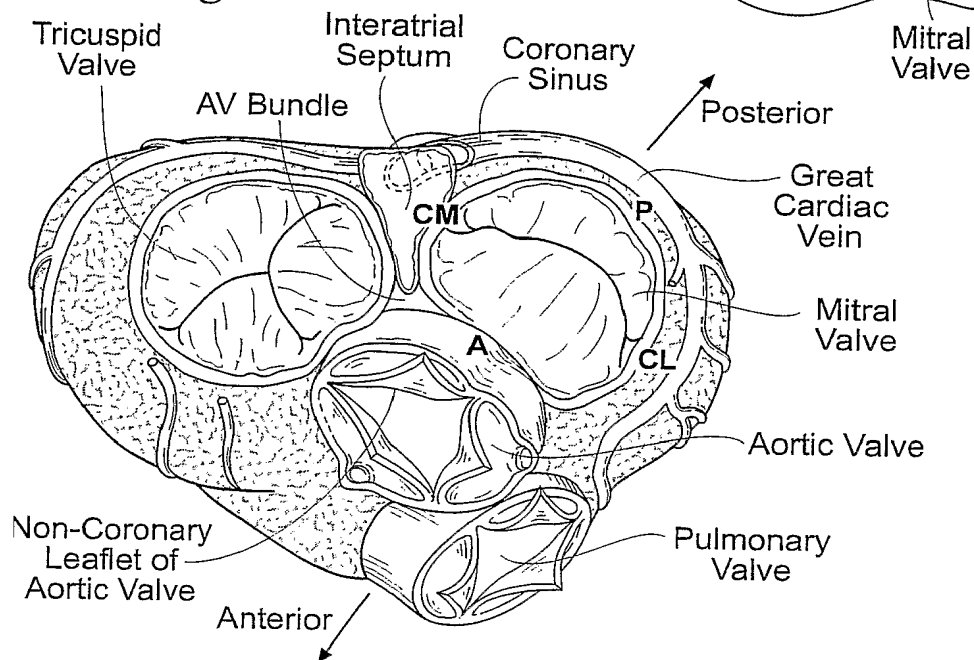
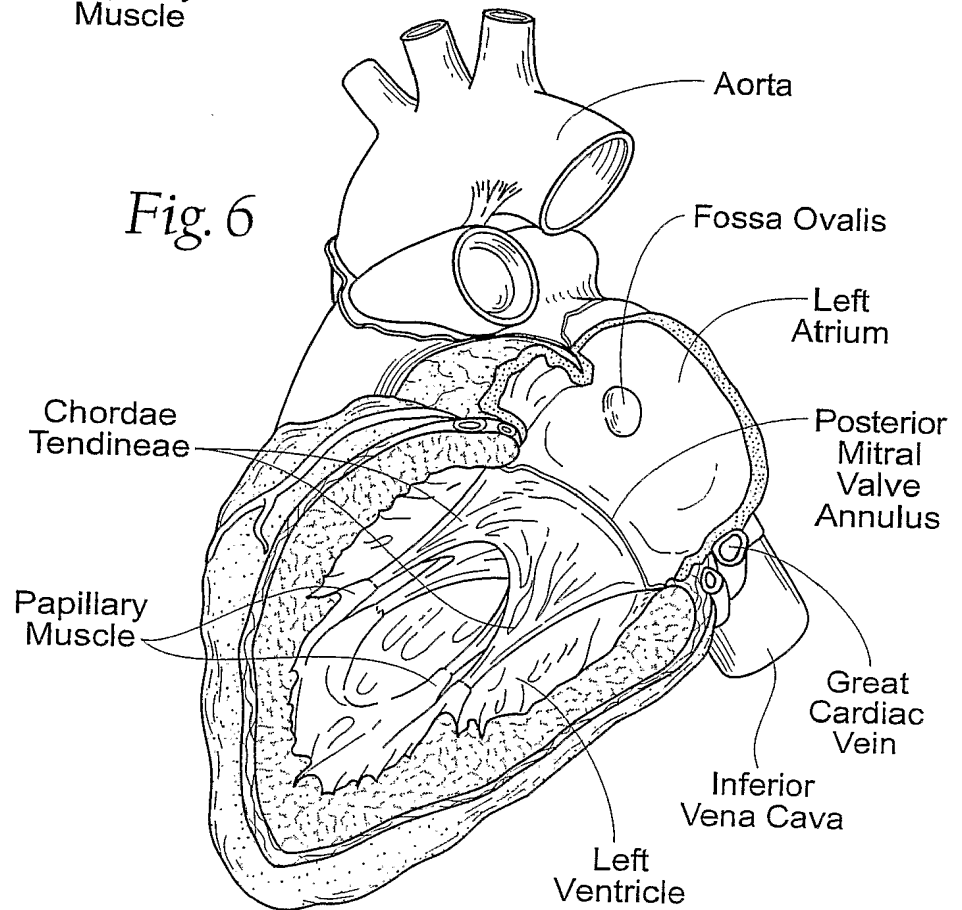
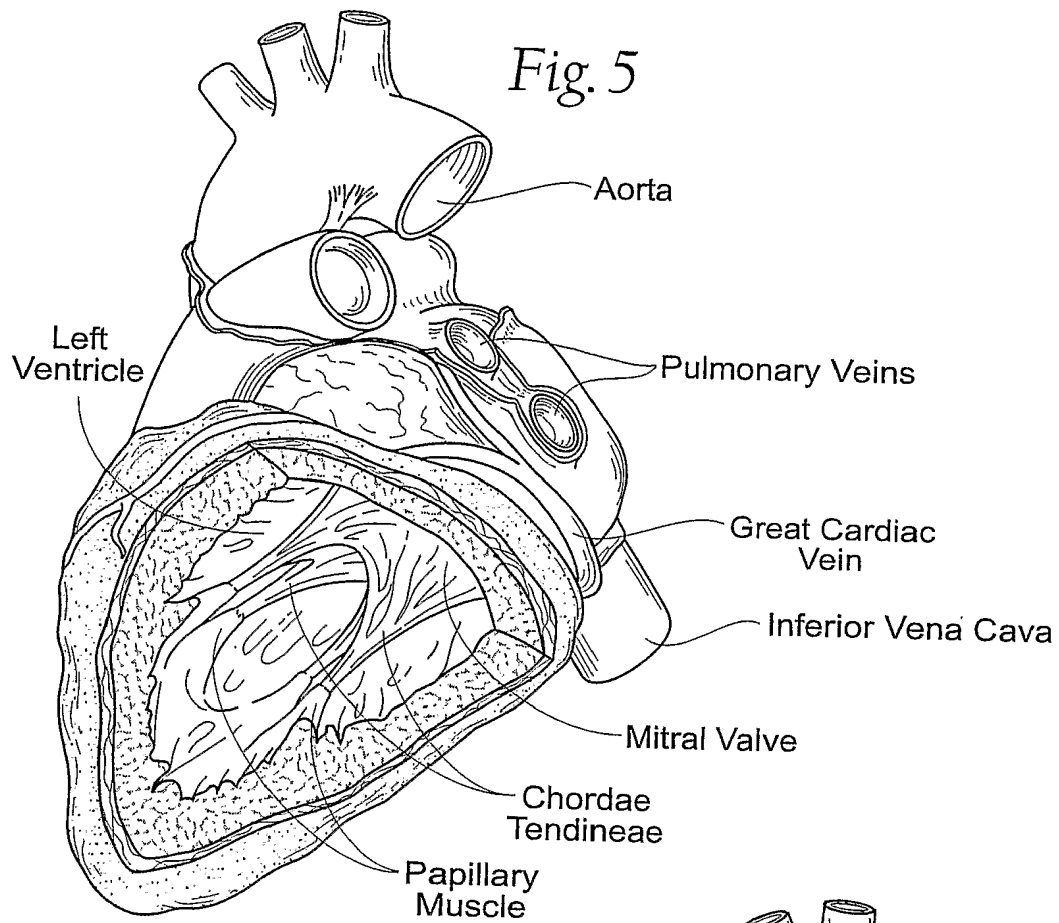


Fig. 4



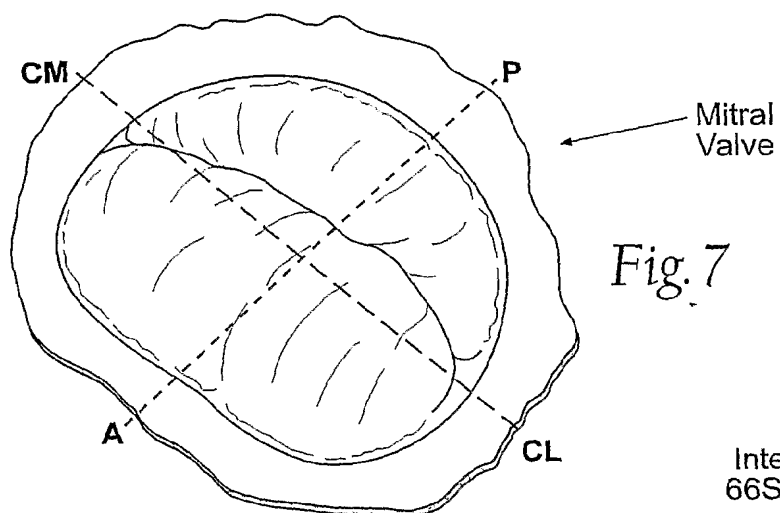


Fig. 7

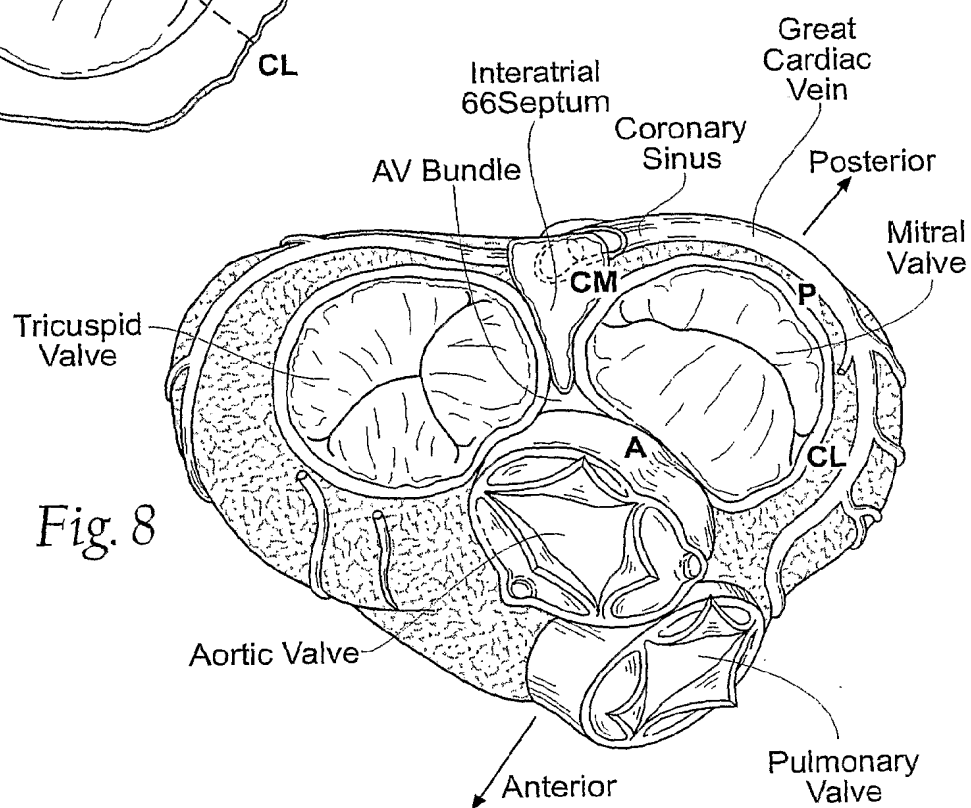


Fig. 8

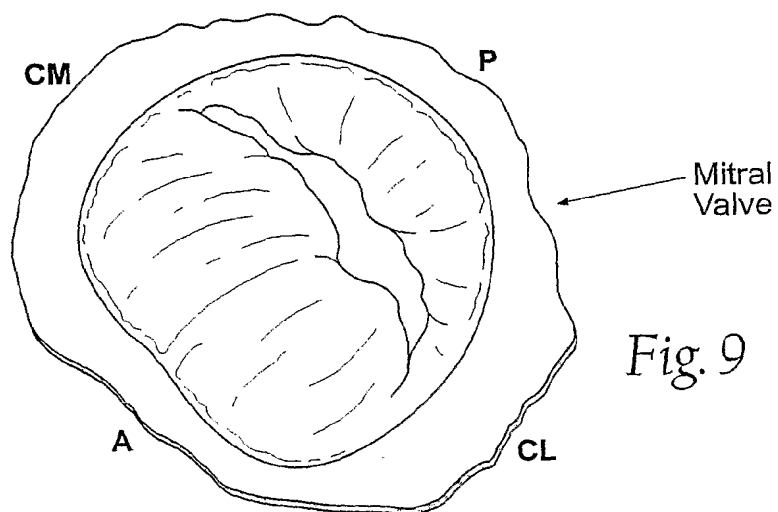
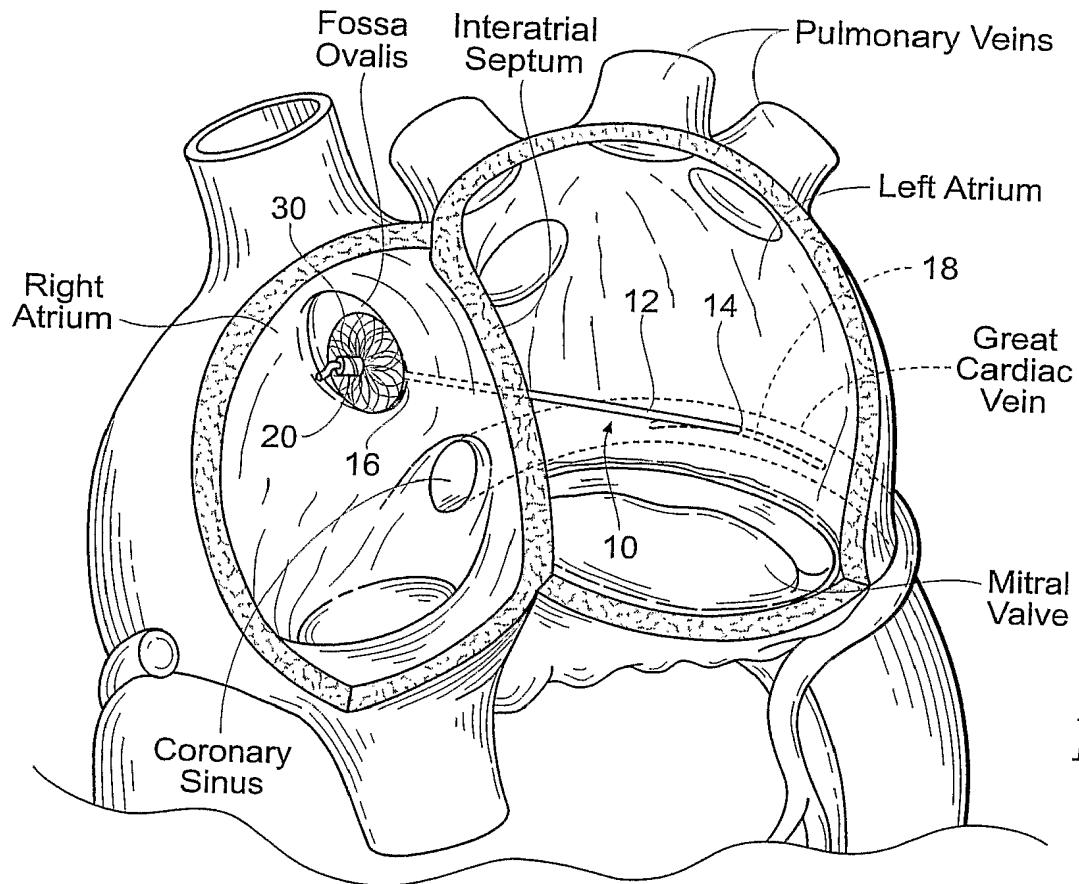
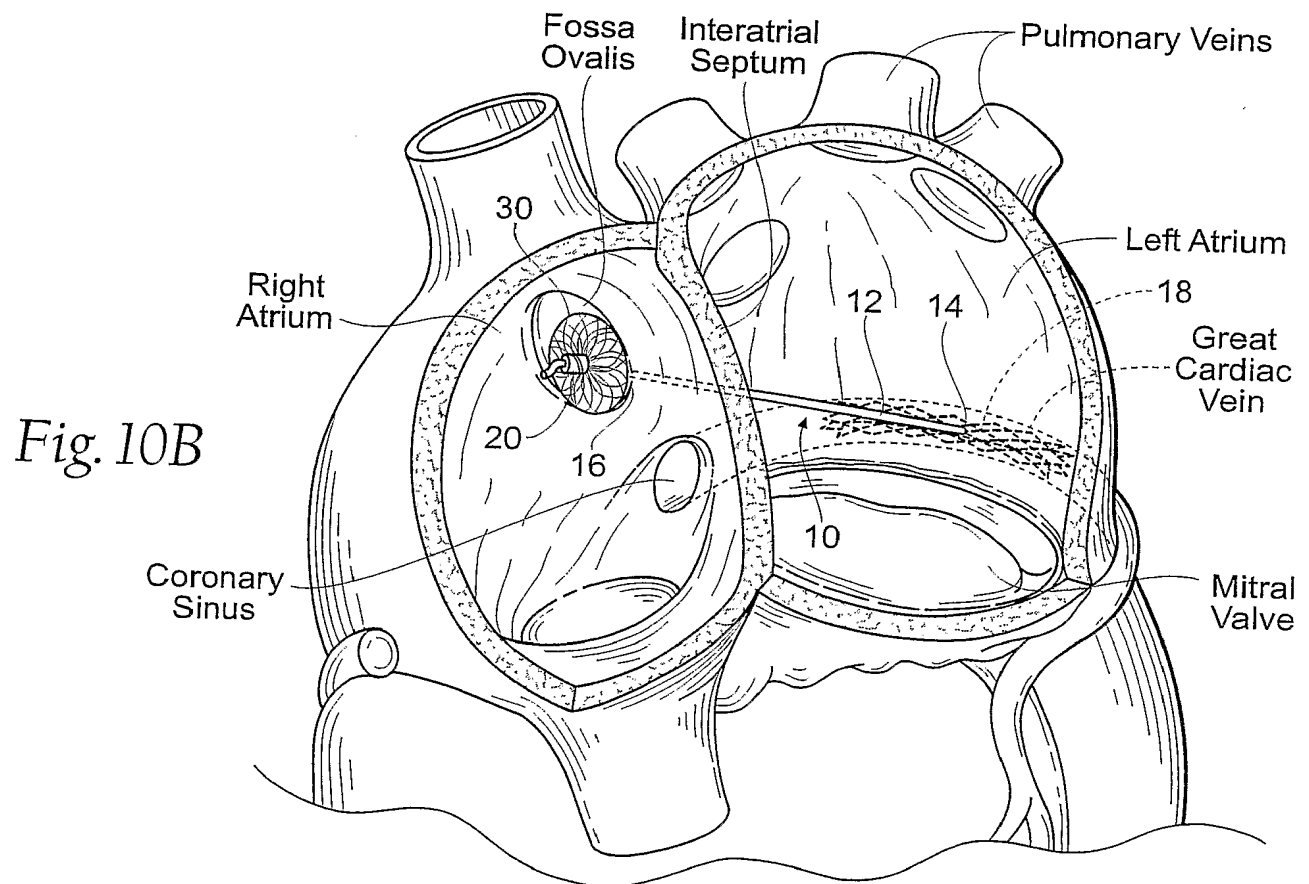
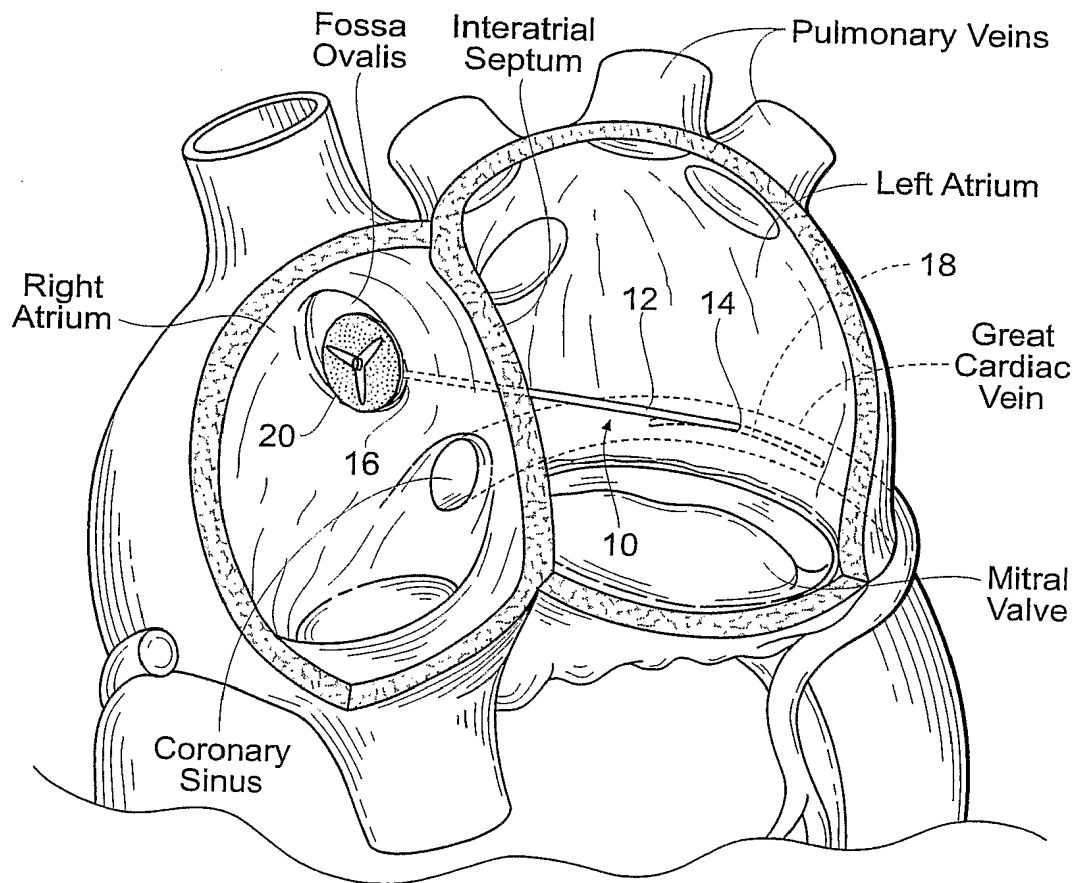
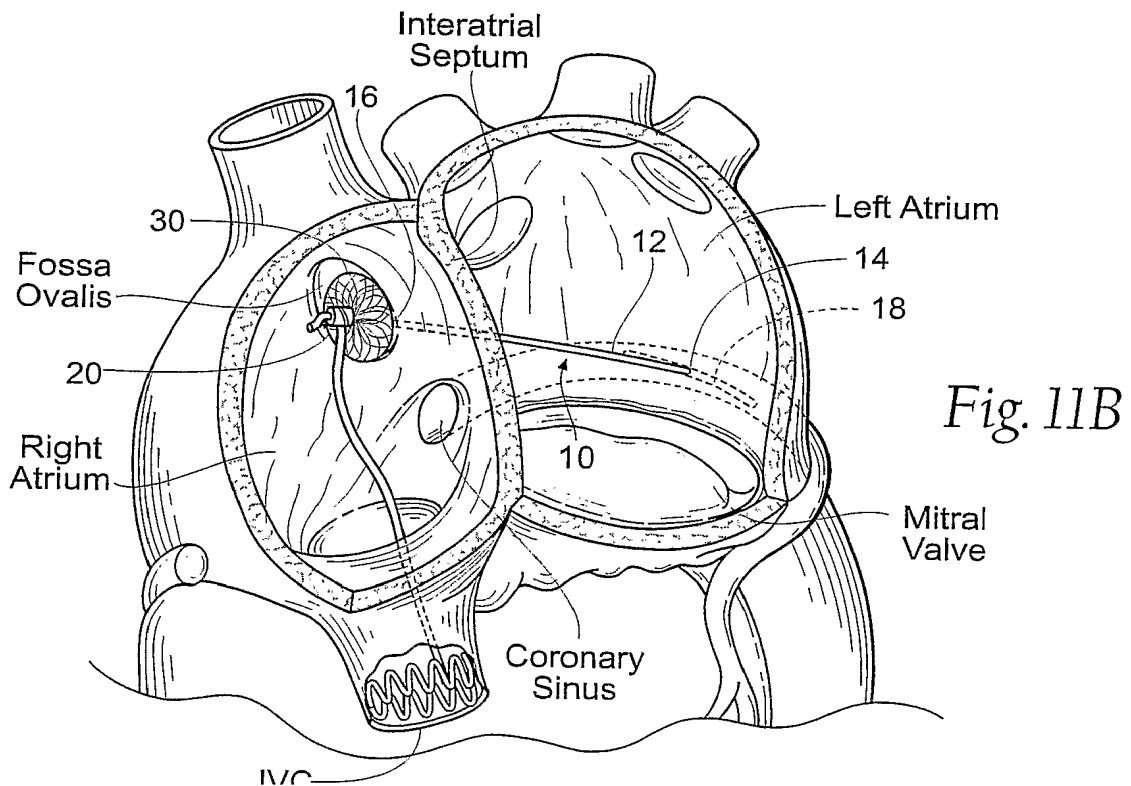
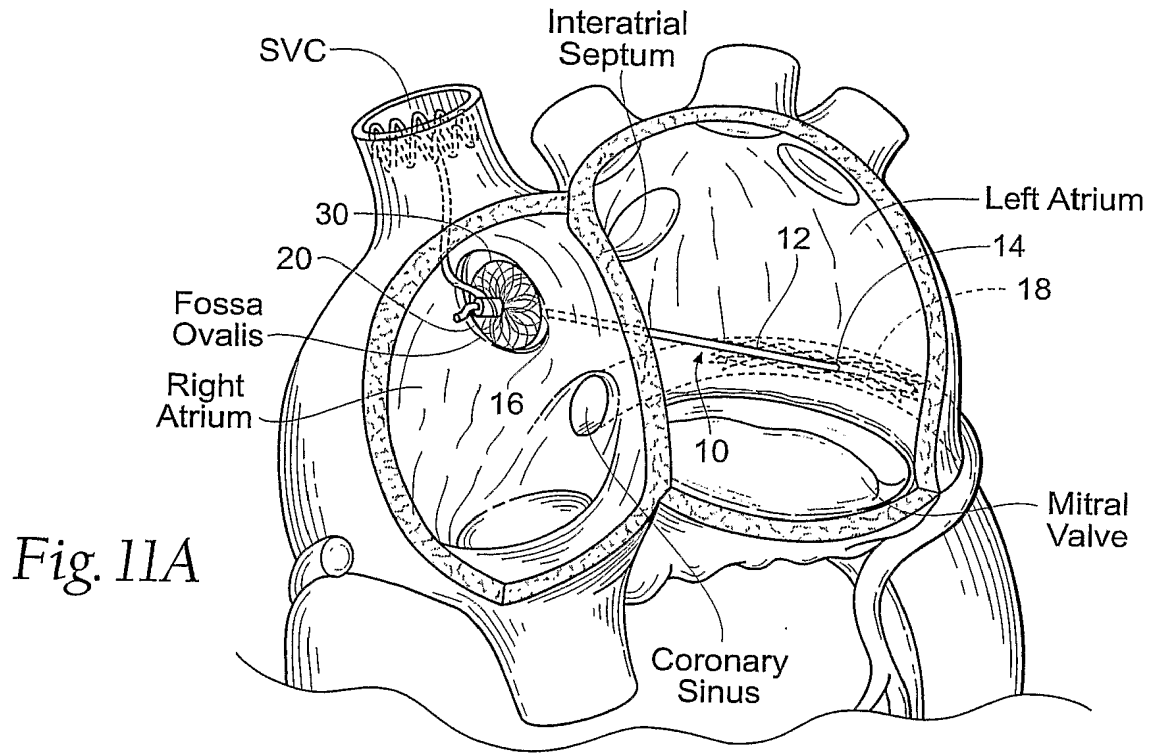


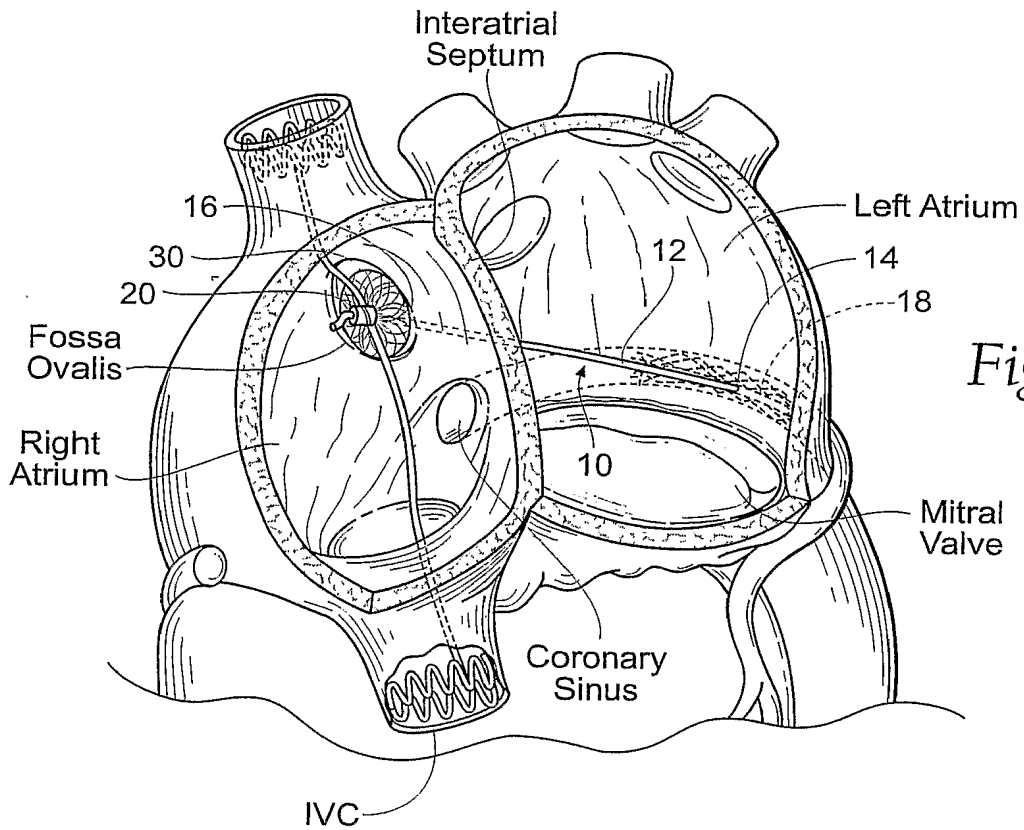
Fig. 9

*Fig. 10A**Fig. 10B*

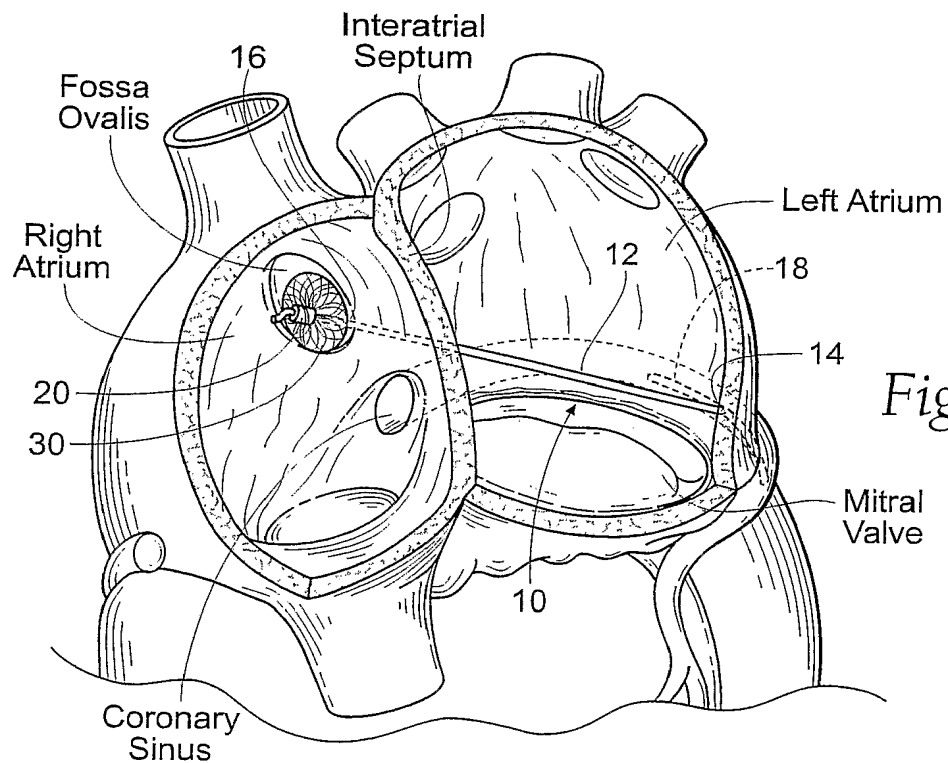
*Fig. 10C*



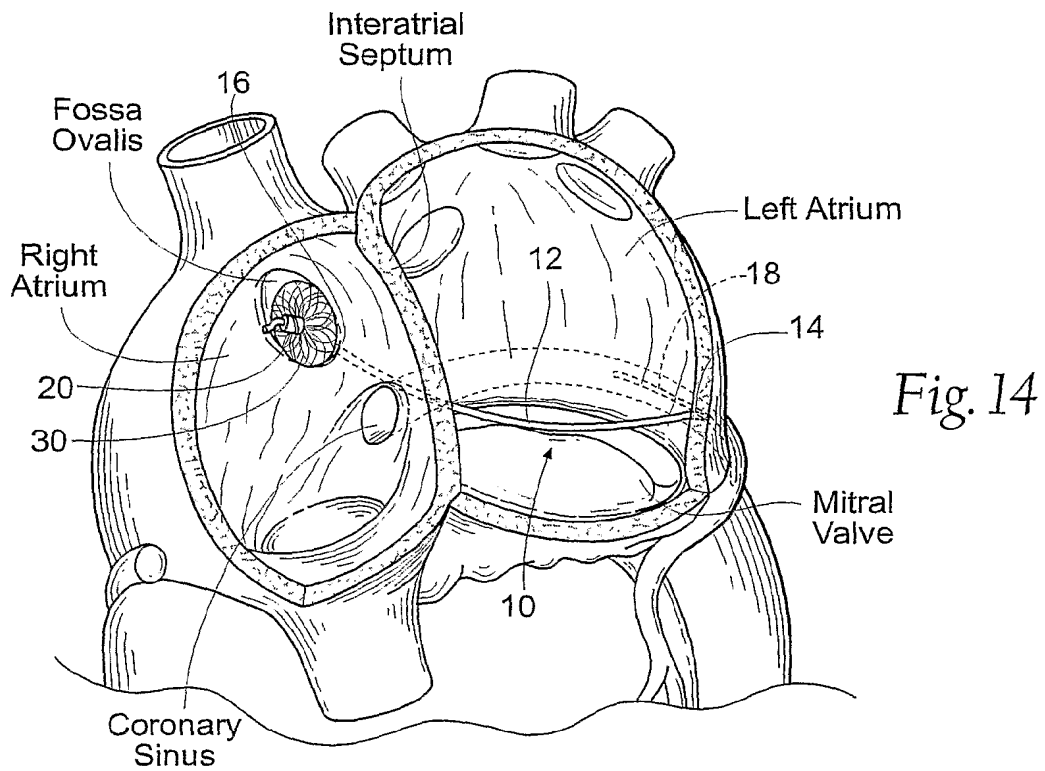
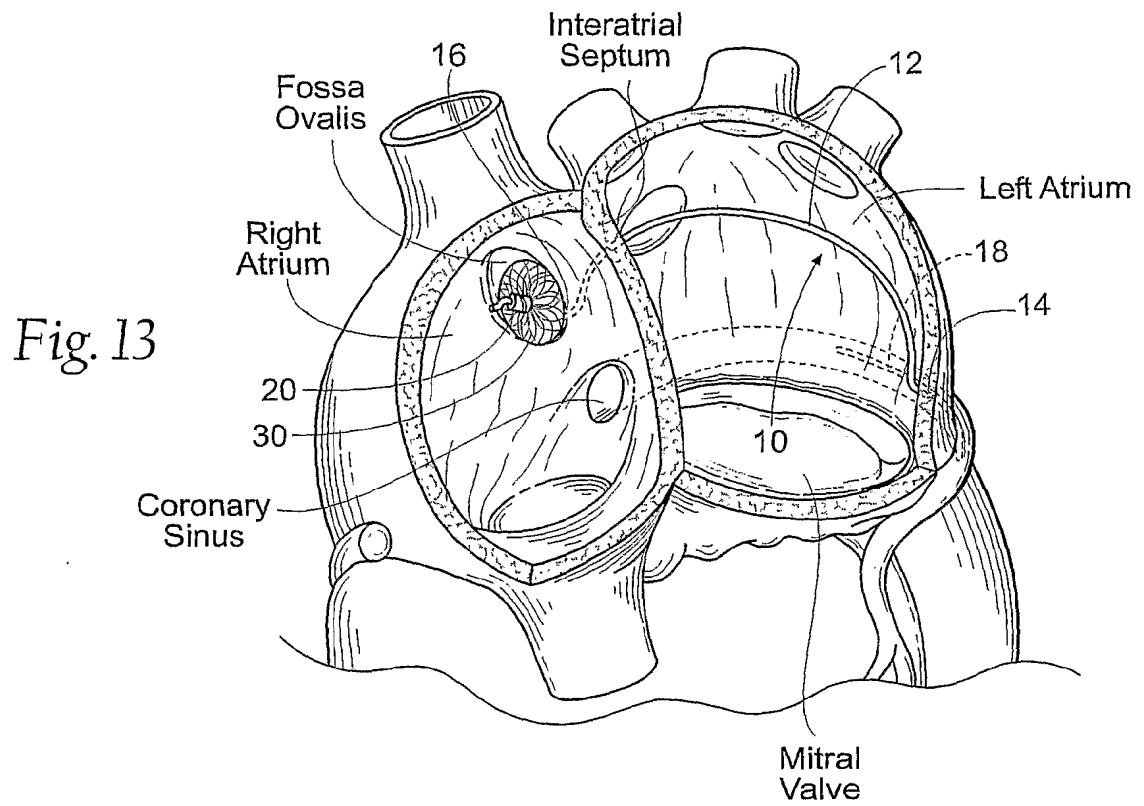


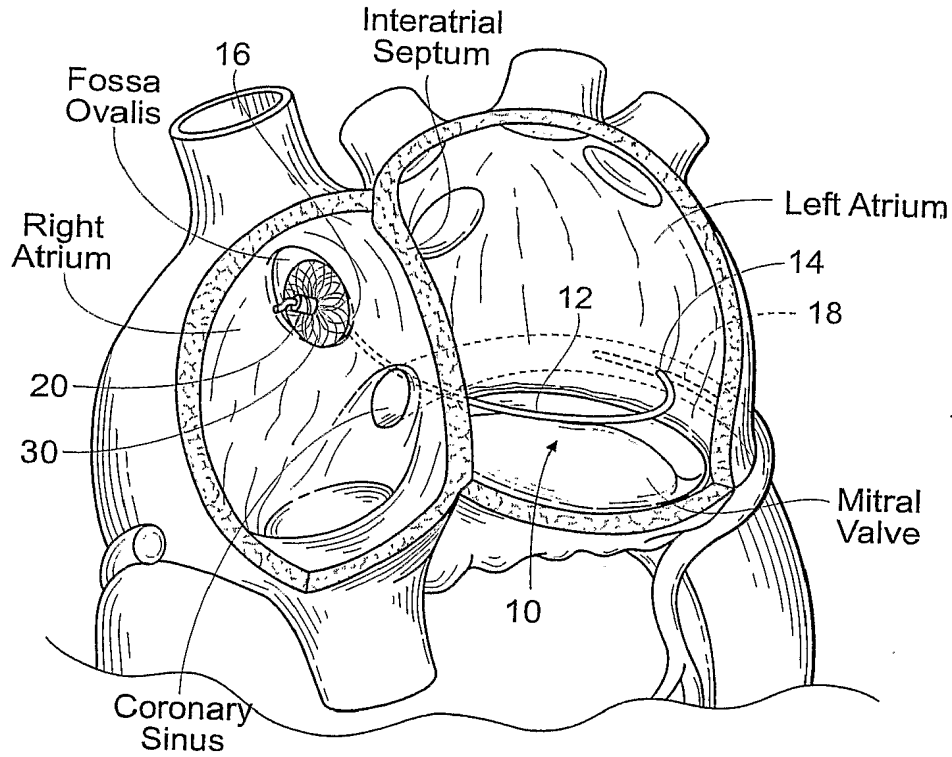


*Fig. 11C*

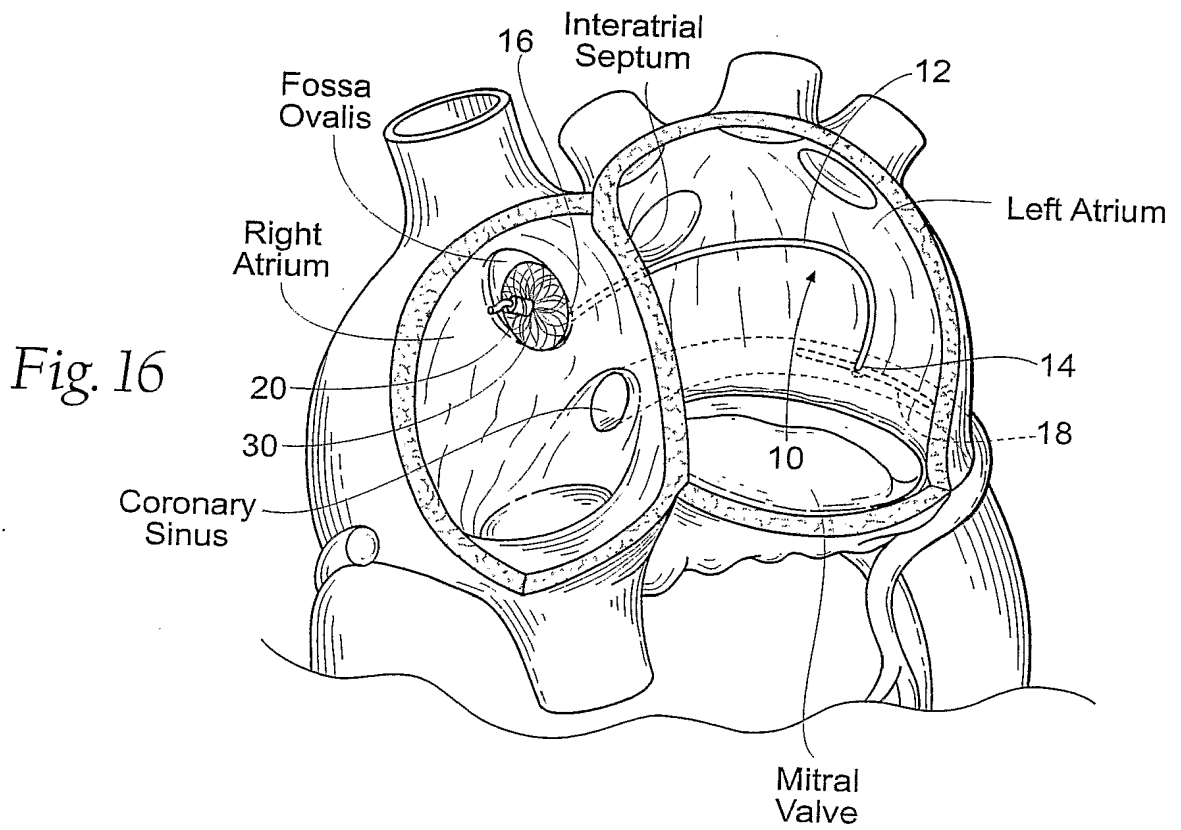


*Fig. 12*

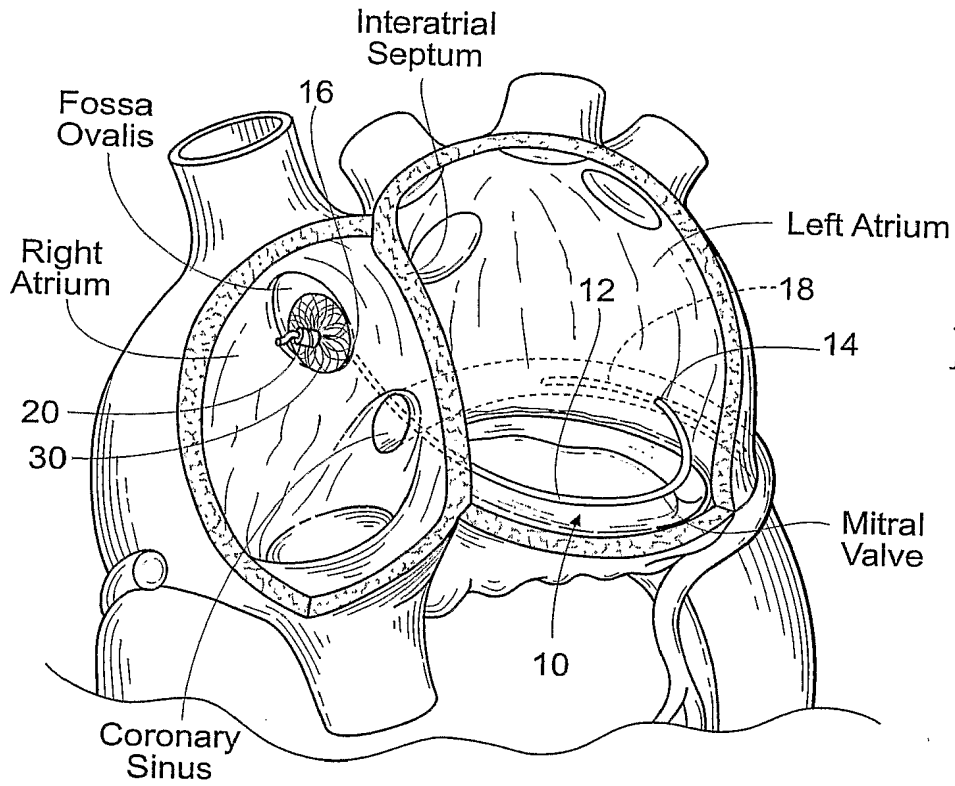




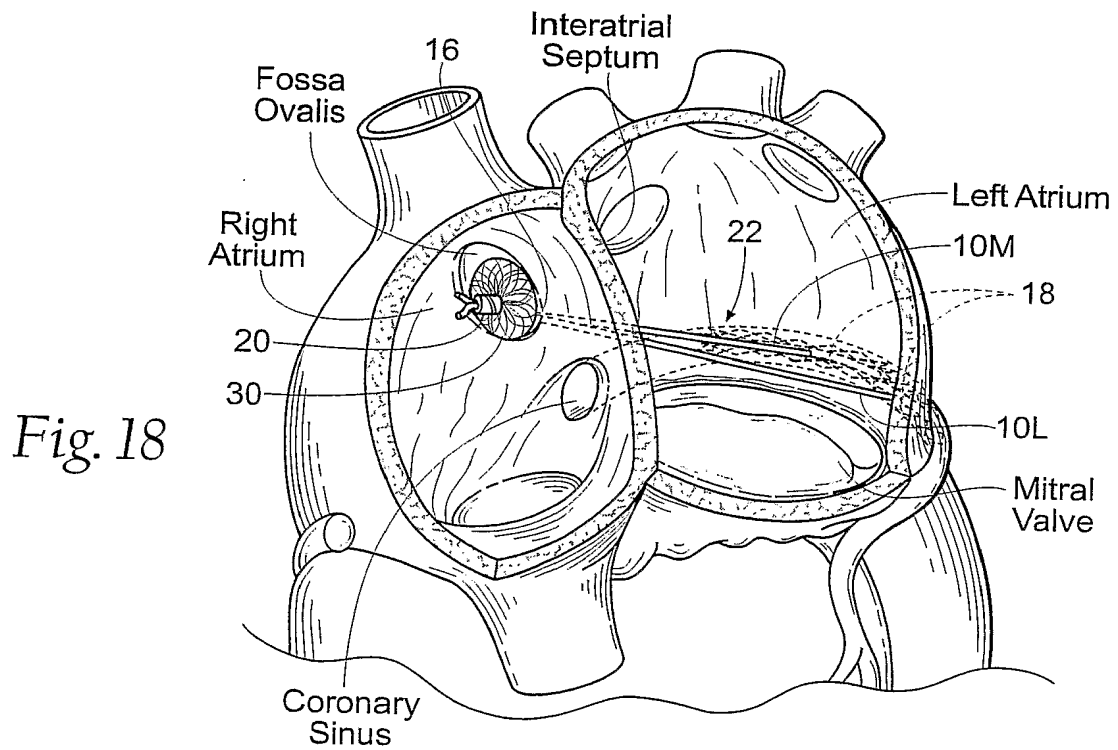
*Fig. 15*



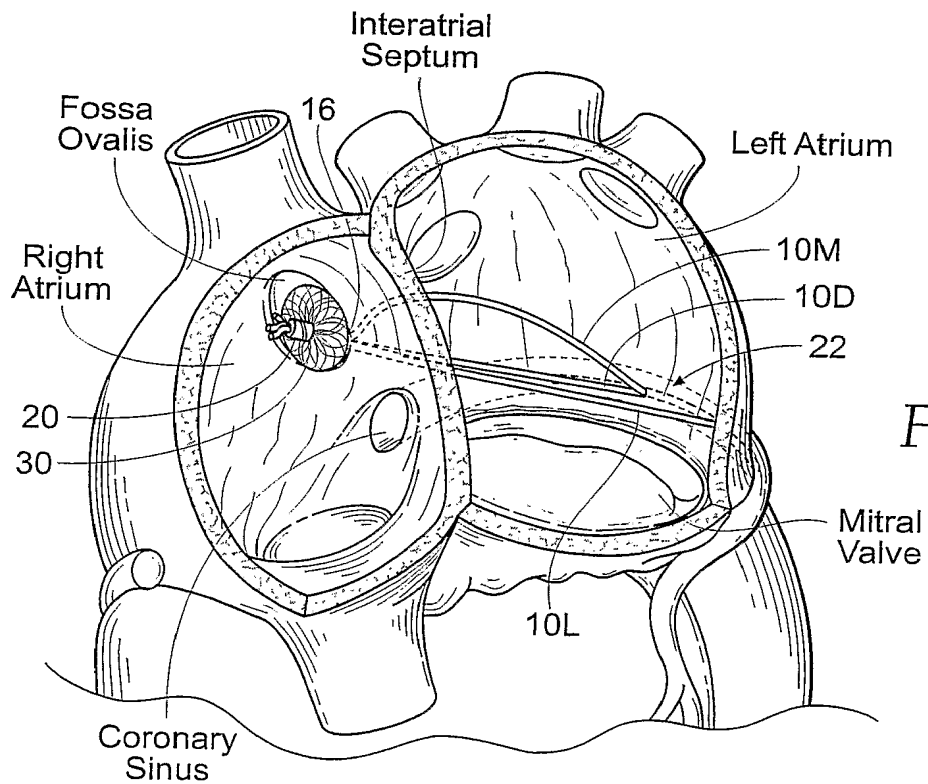
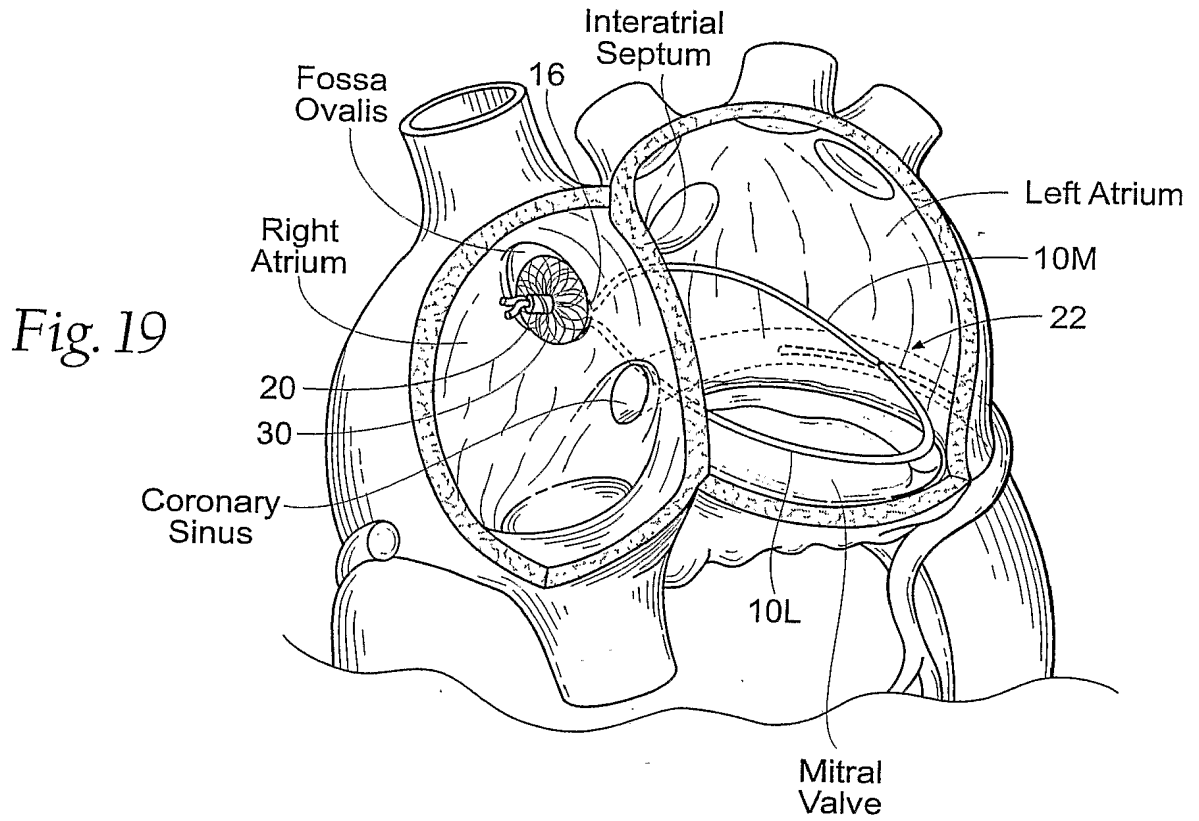
*Fig. 16*



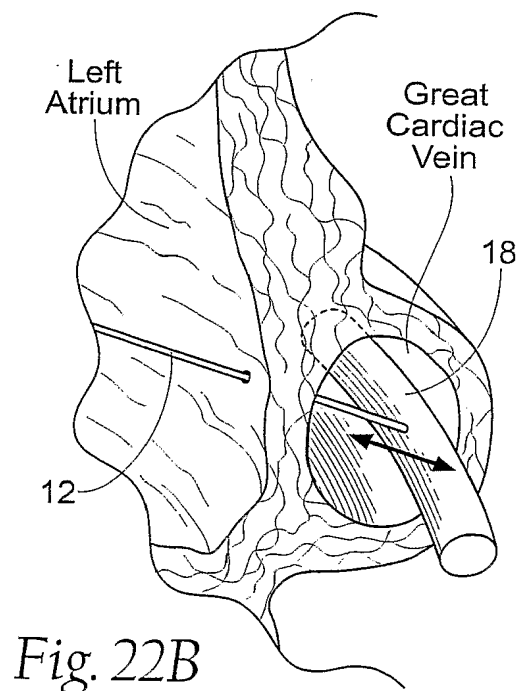
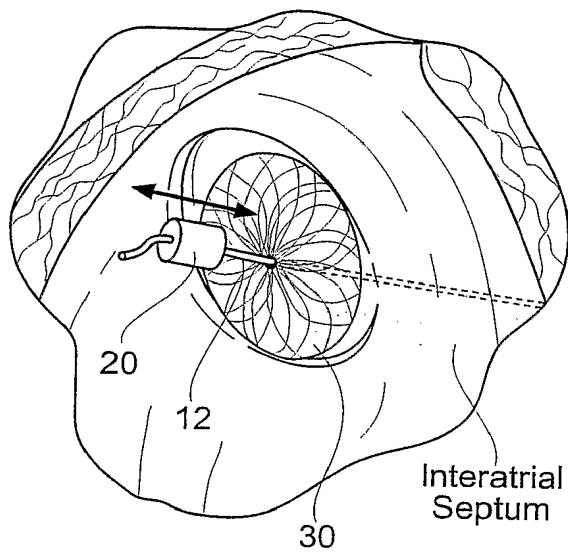
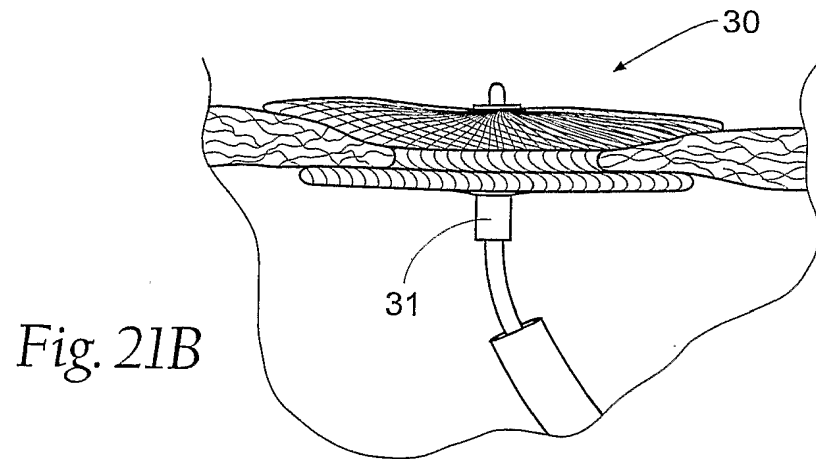
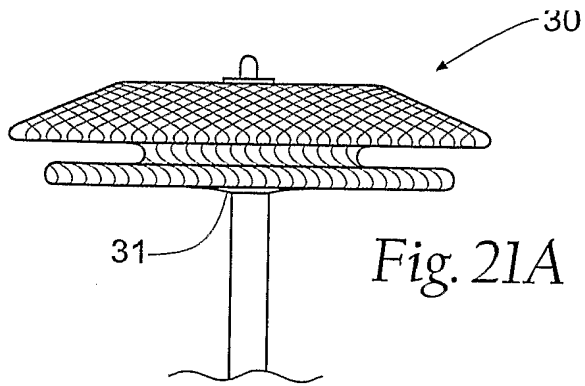
*Fig. 17*



*Fig. 18*



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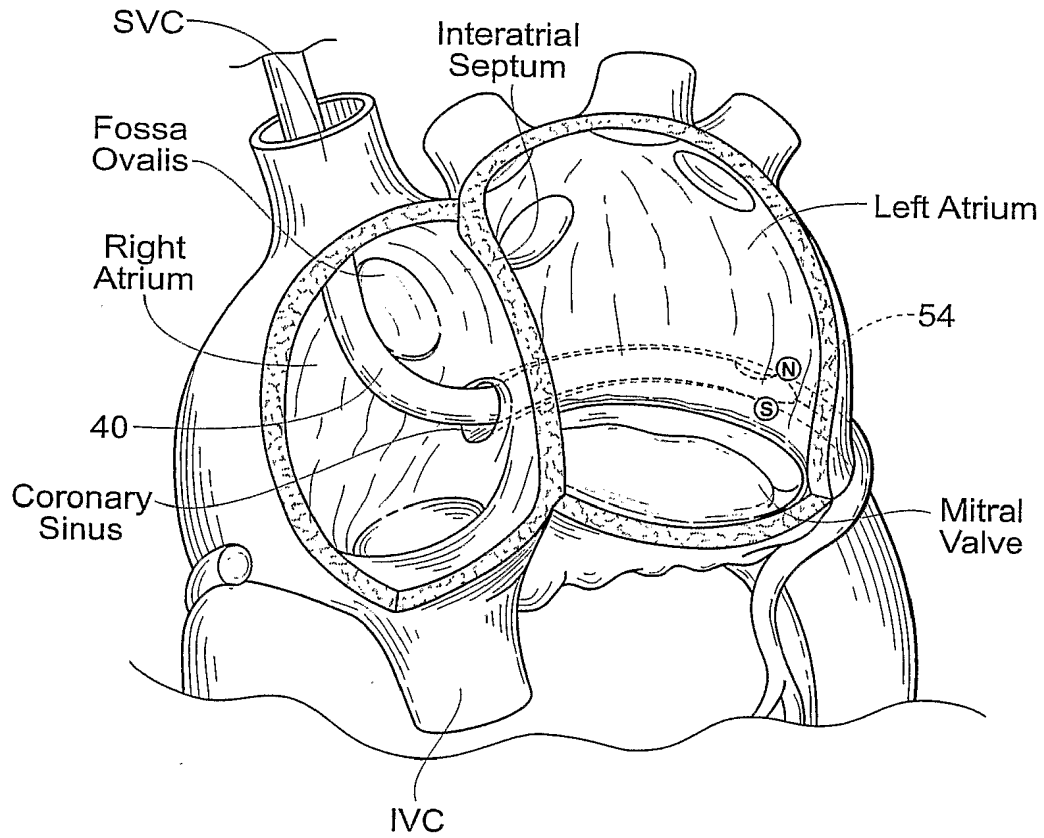


Fig. 23

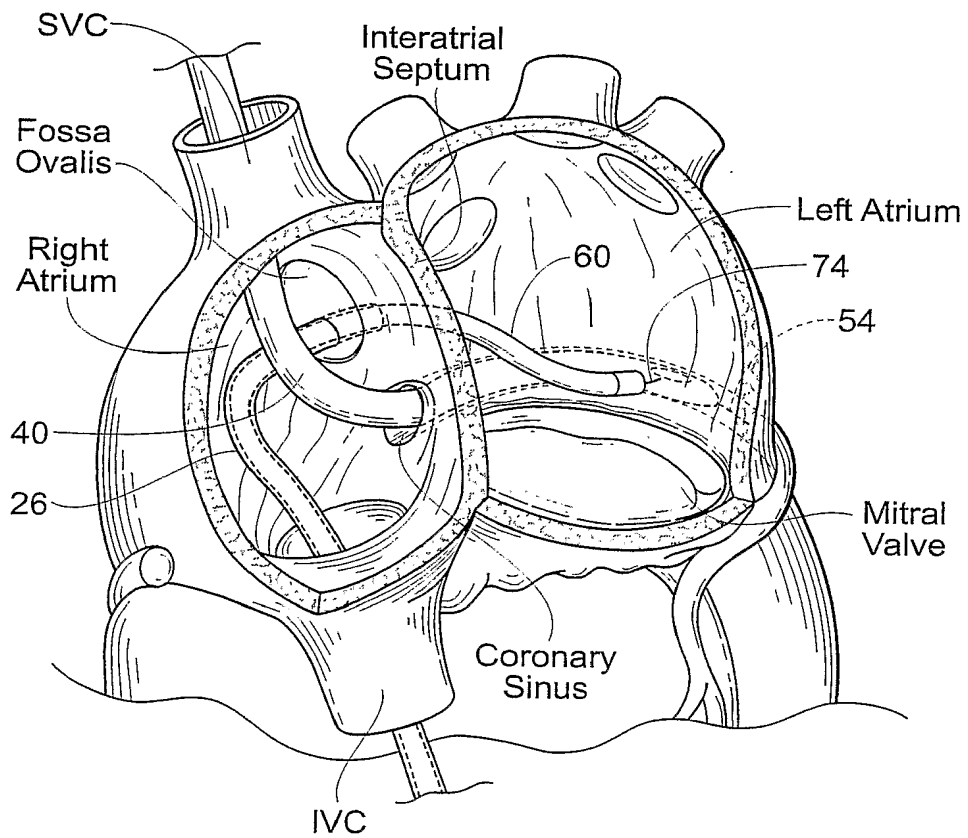


Fig. 24



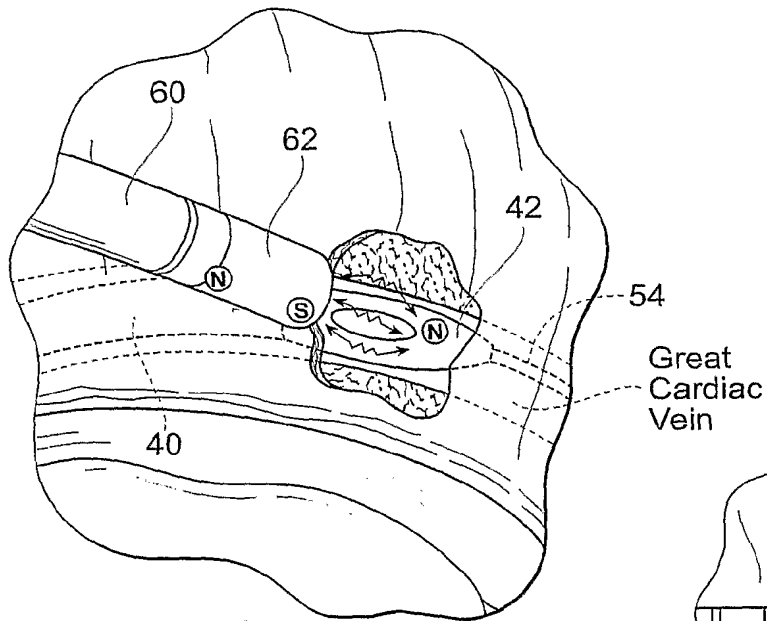


Fig. 25

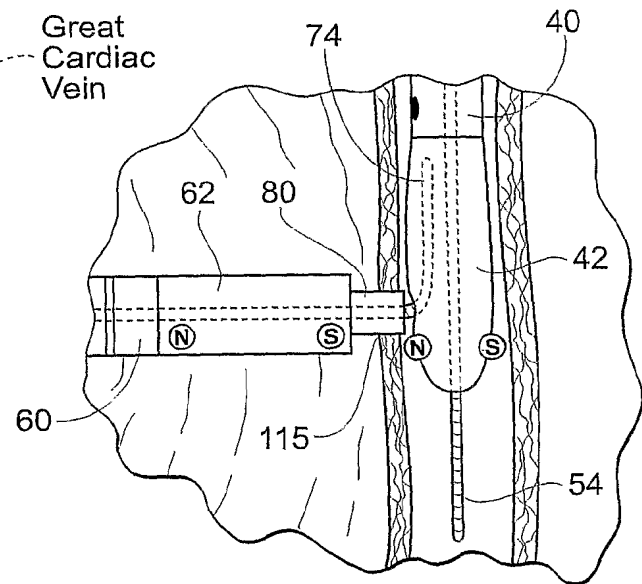


Fig. 26

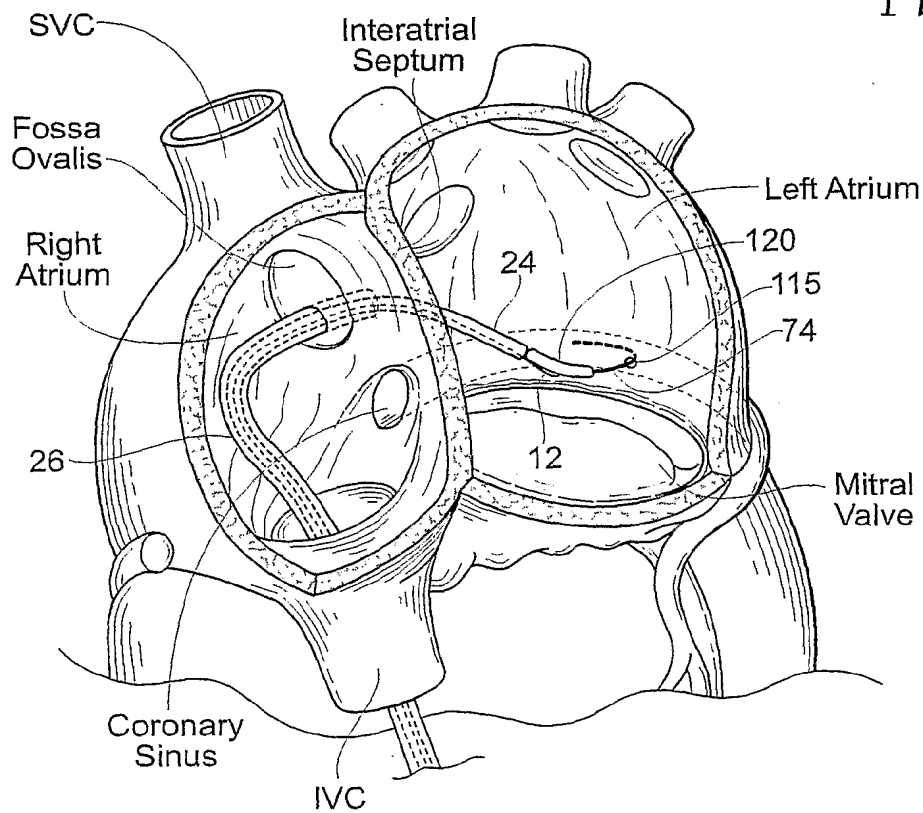


Fig. 27

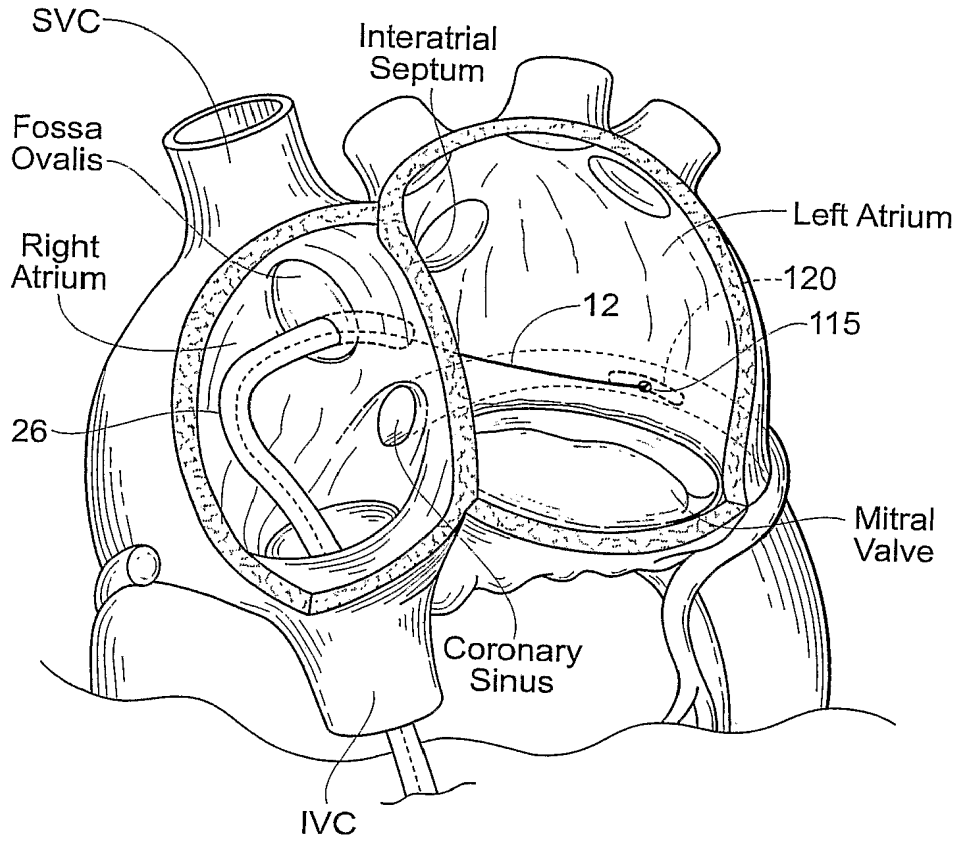


Fig. 28

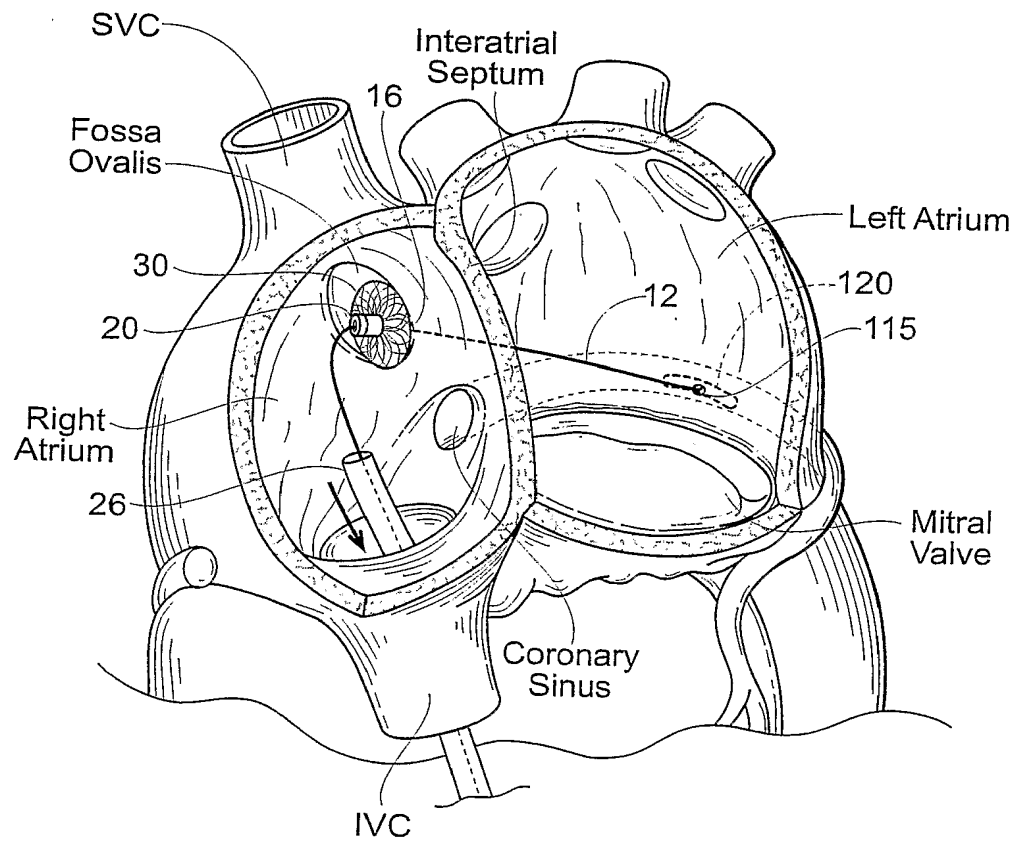
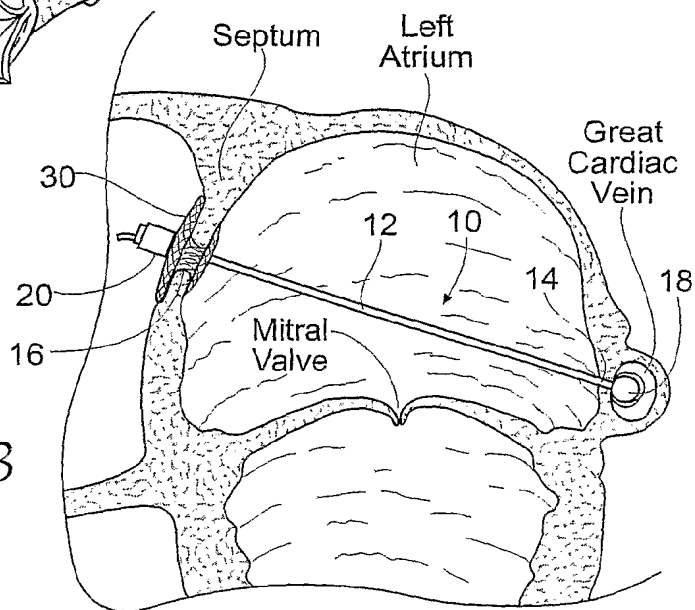
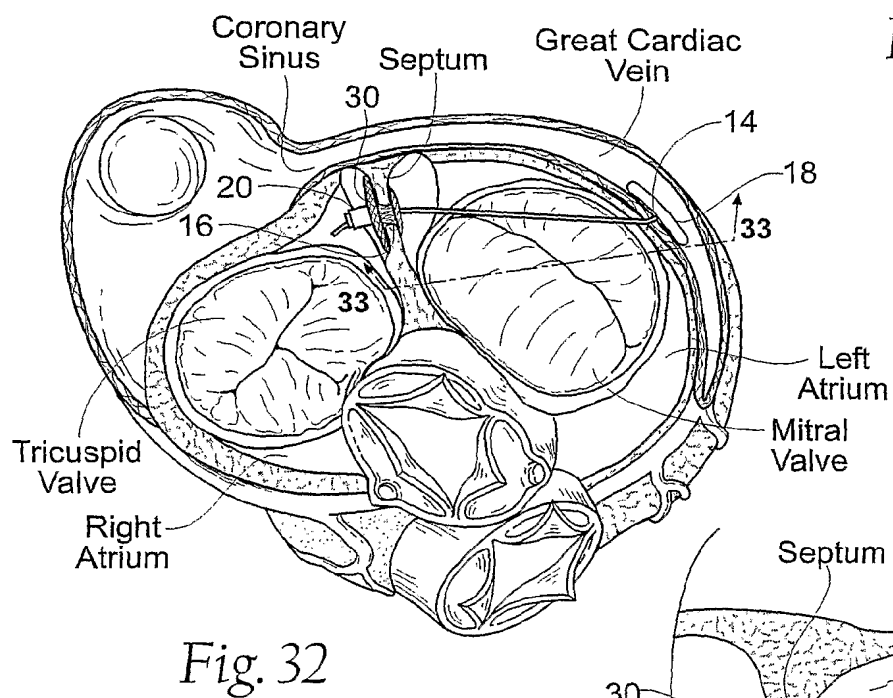
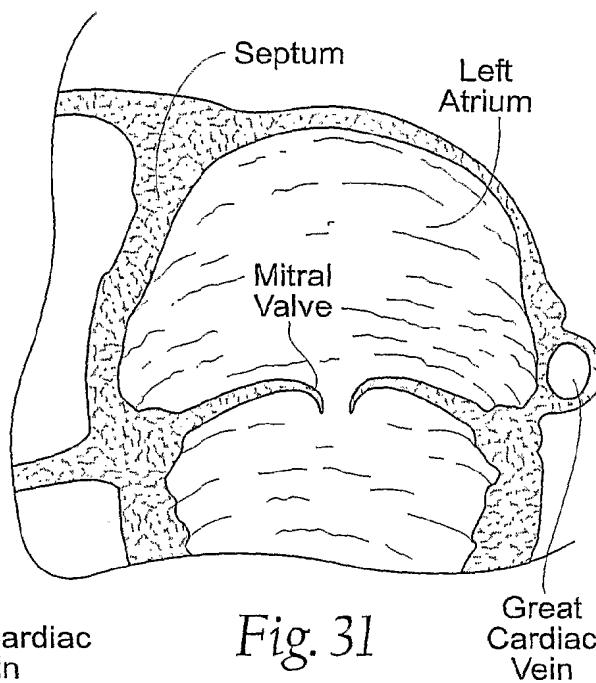
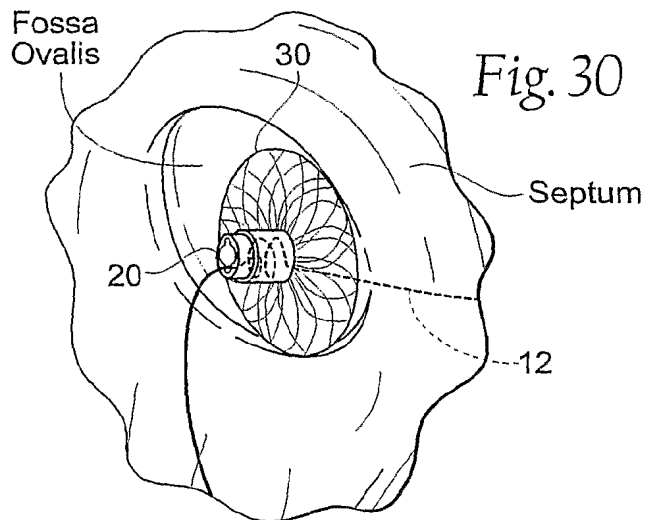


Fig. 29



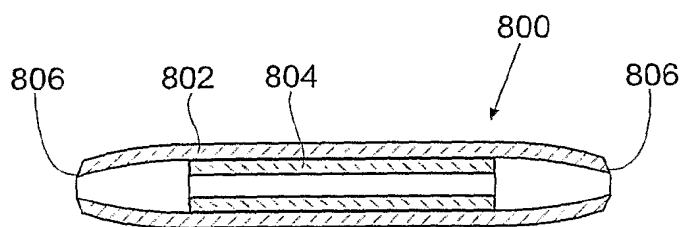


Fig. 34A

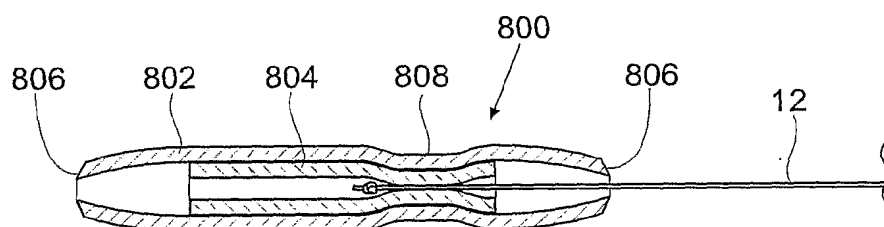


Fig. 34B

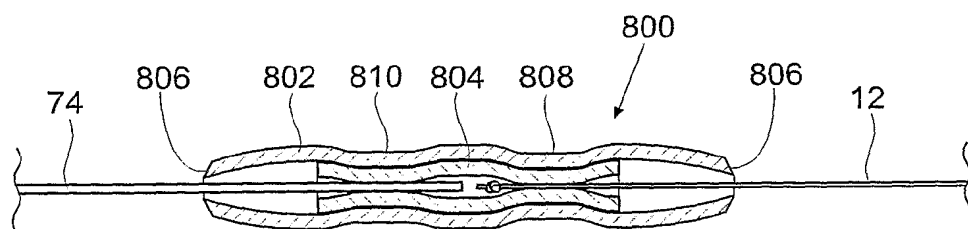


Fig. 34C

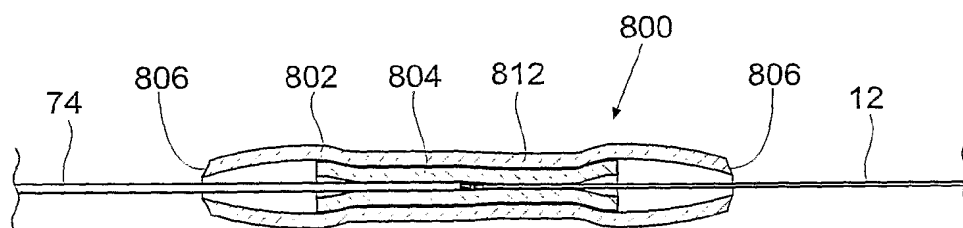


Fig. 34D

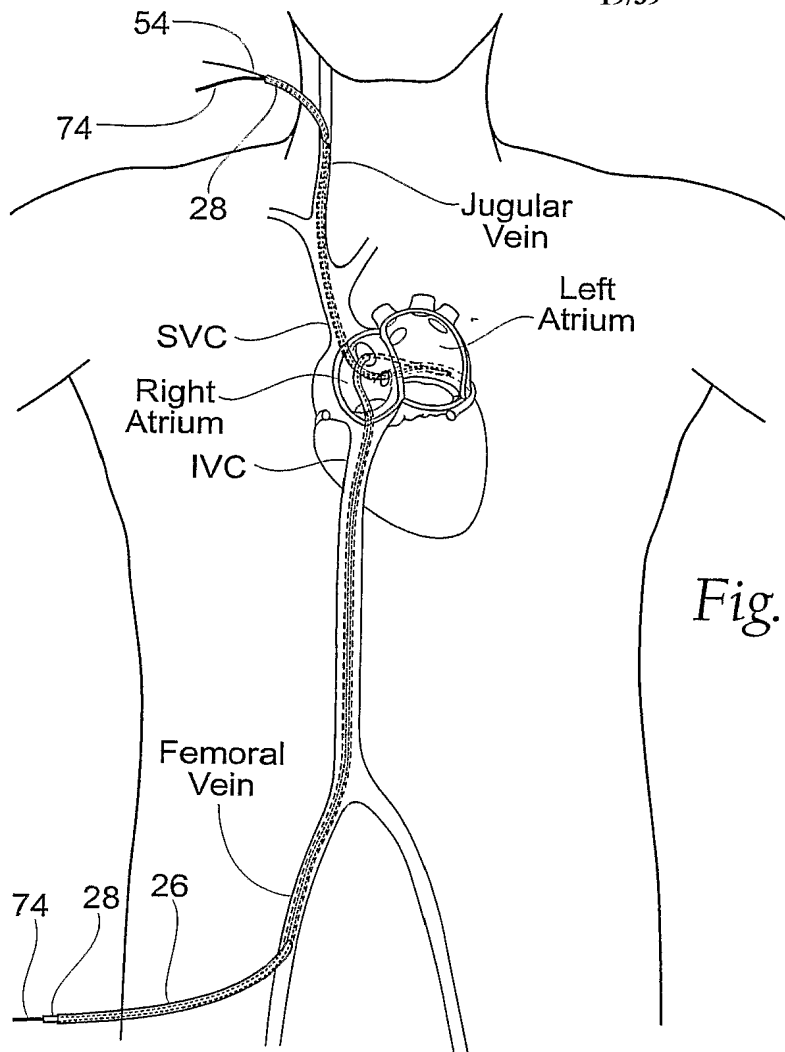


Fig. 35A

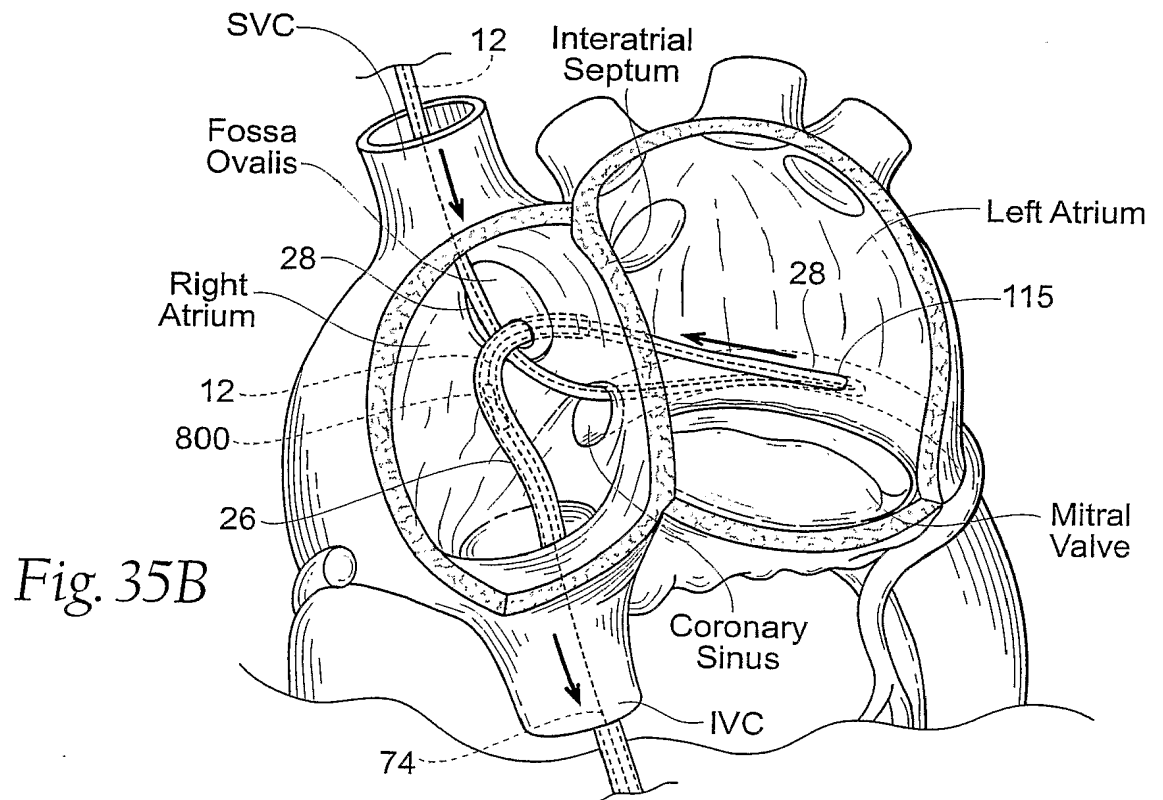


Fig. 35B

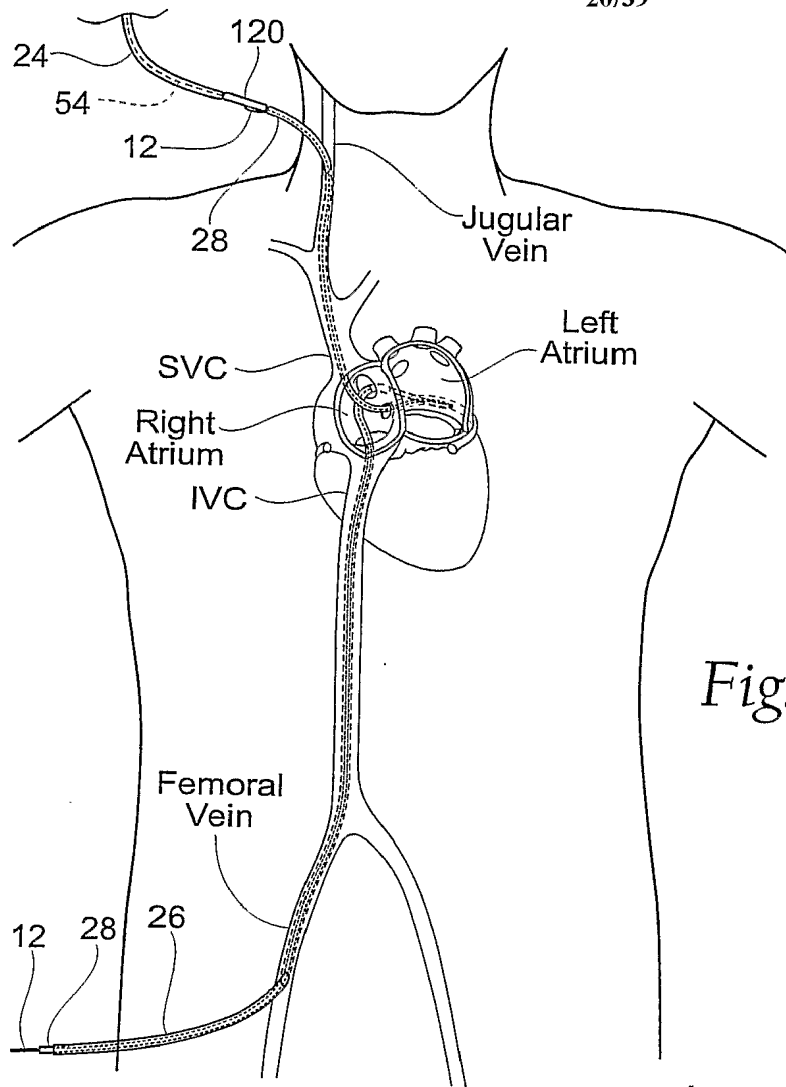


Fig. 36A

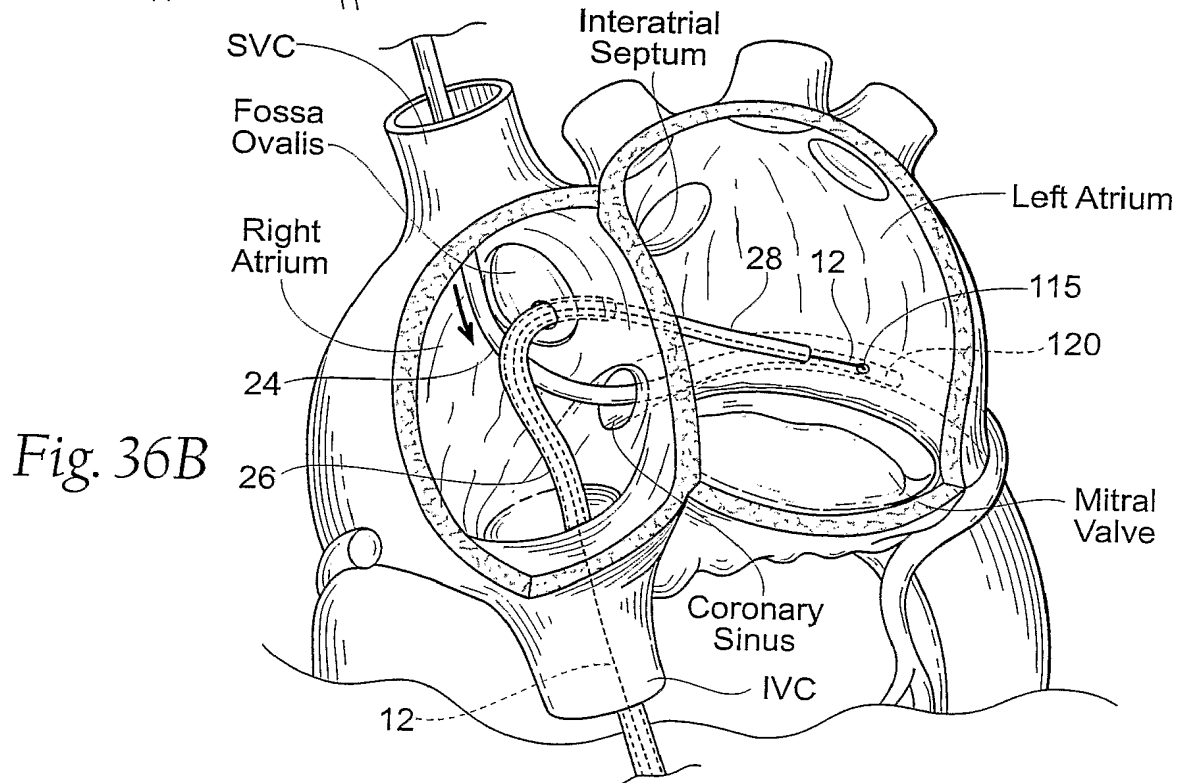
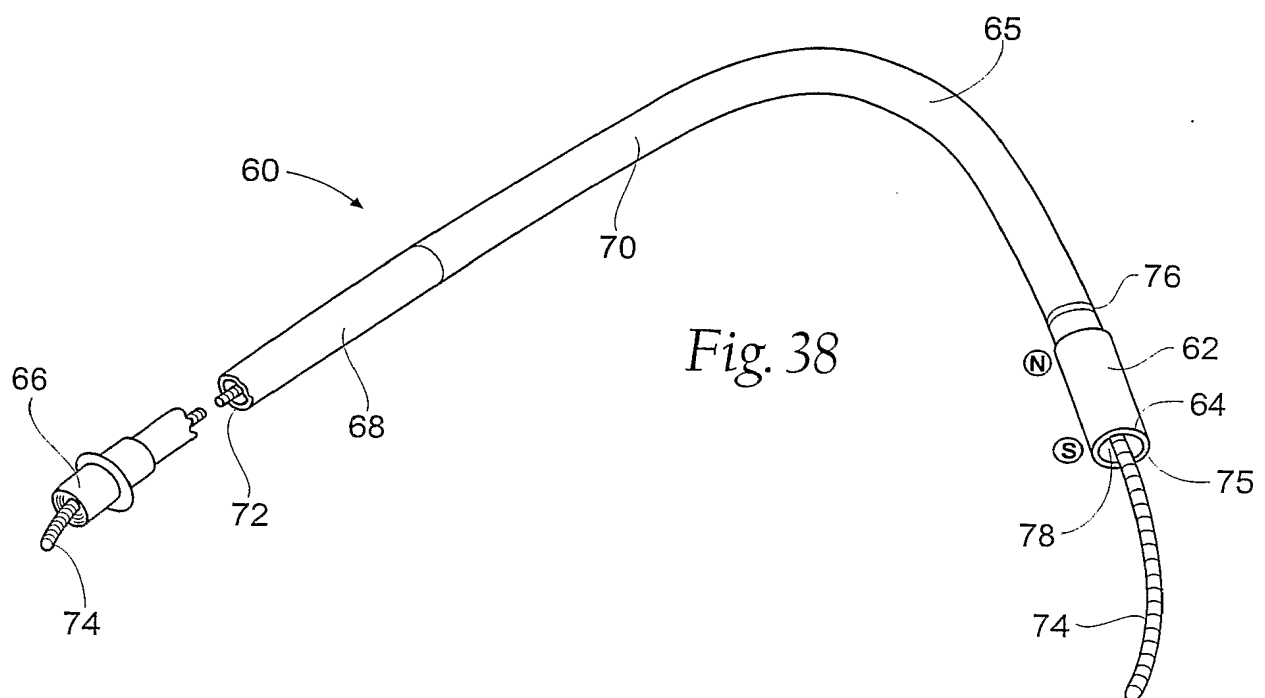
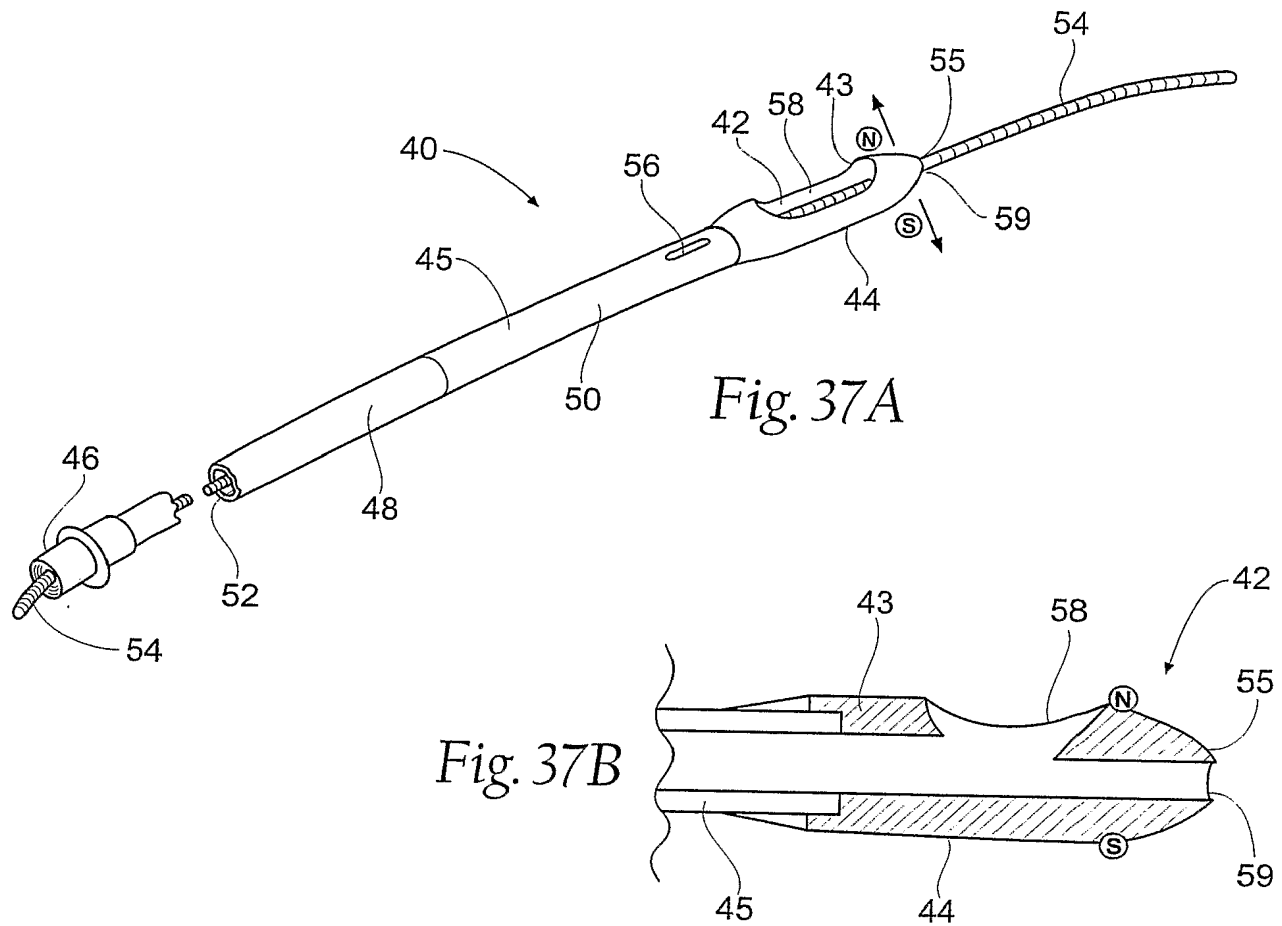
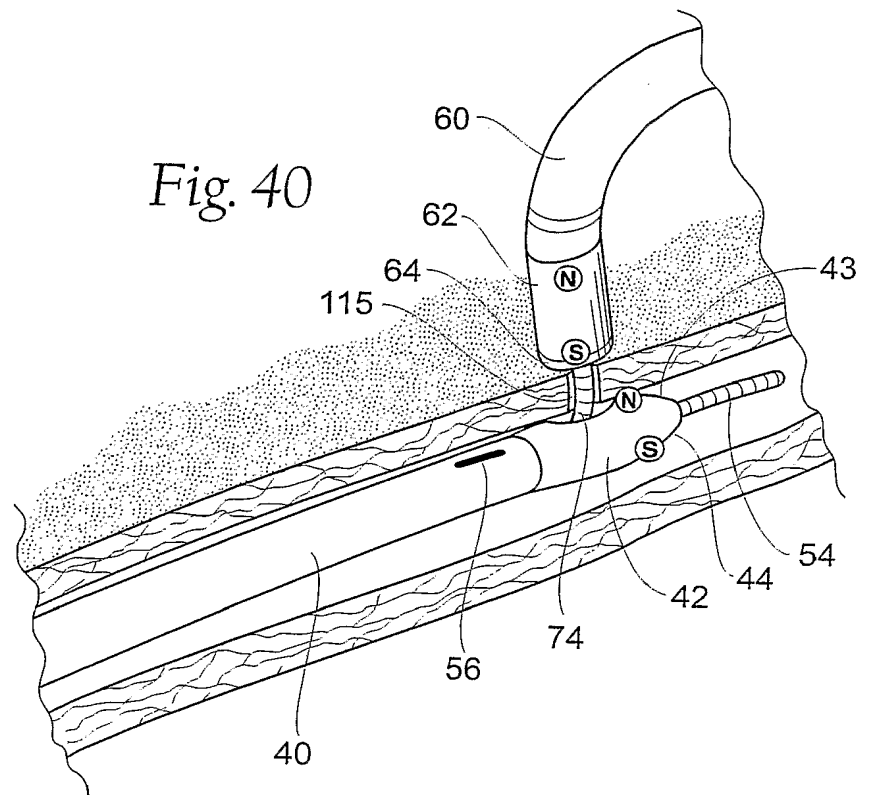
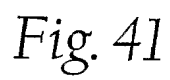
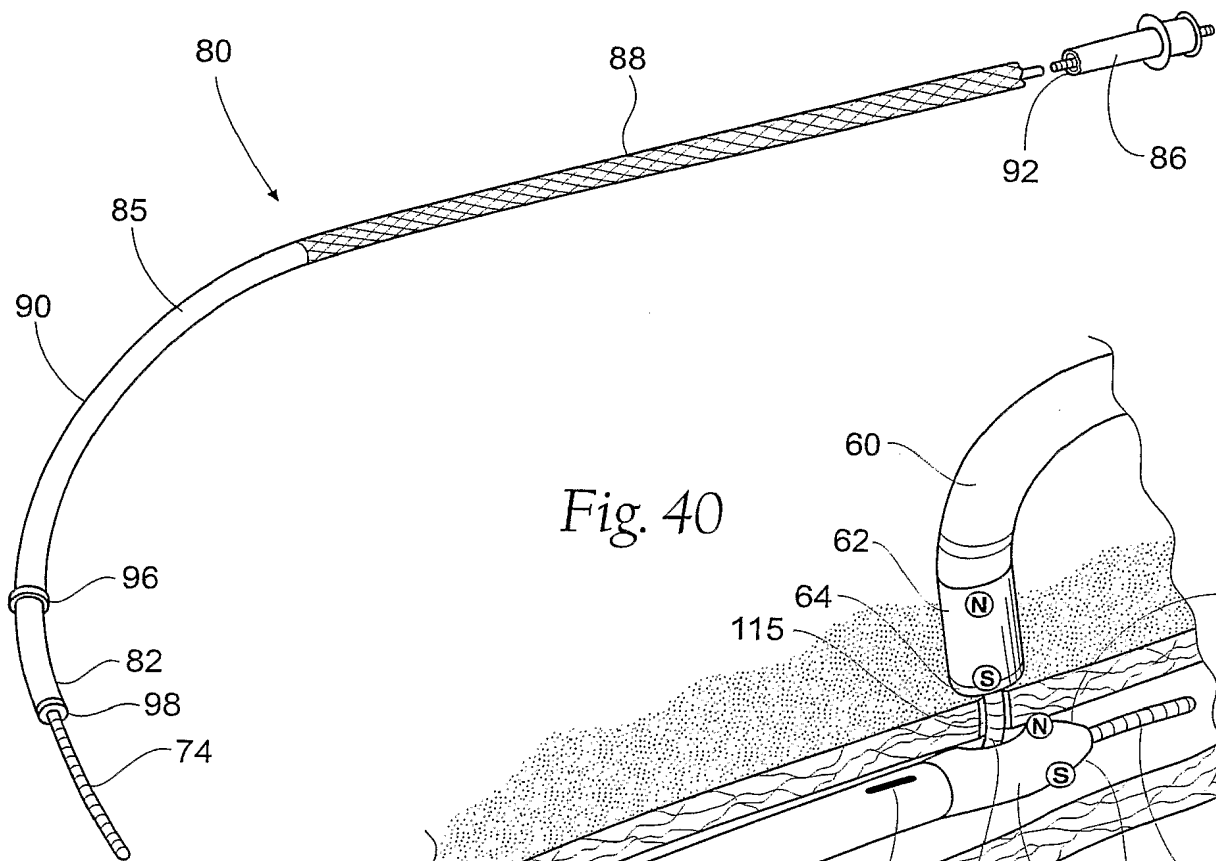
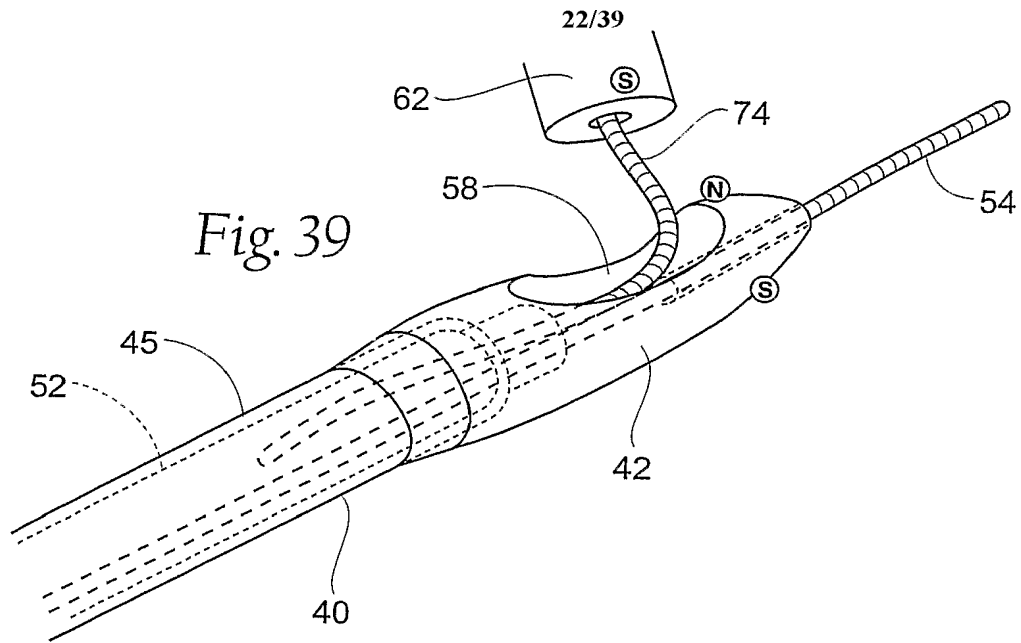
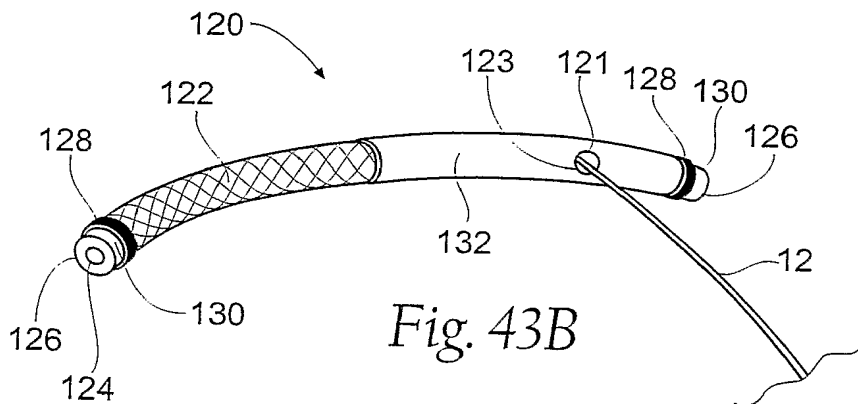
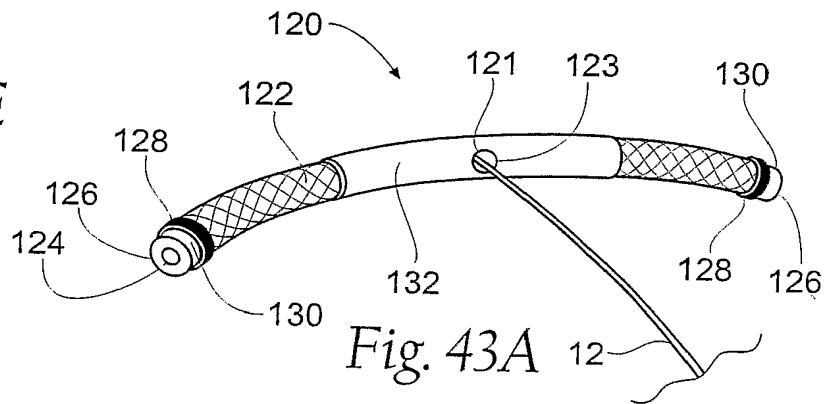
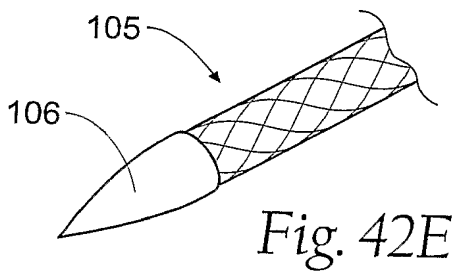
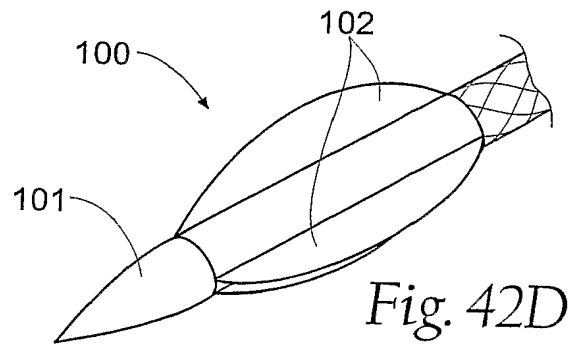
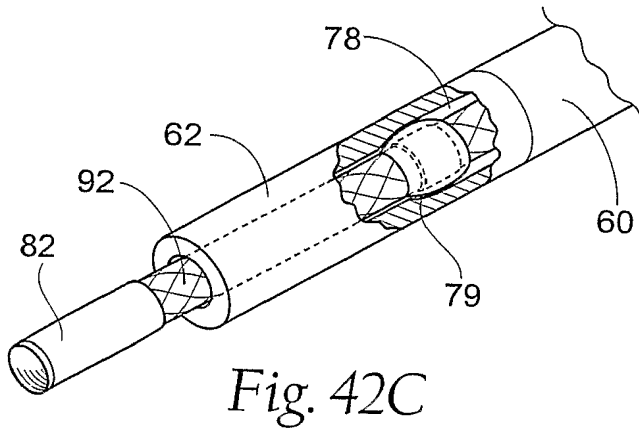
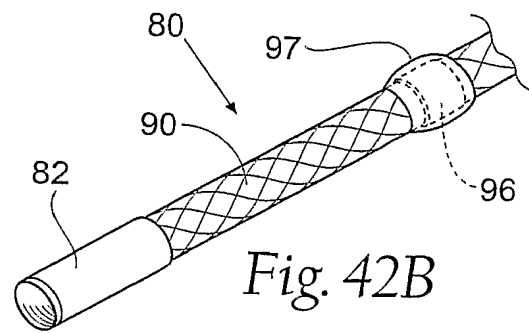
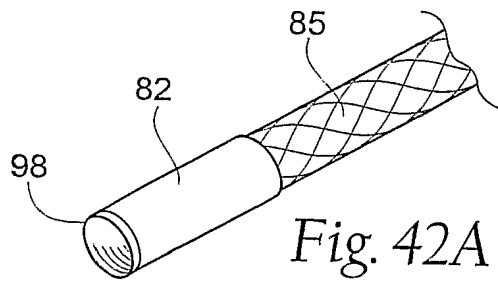


Fig. 36B









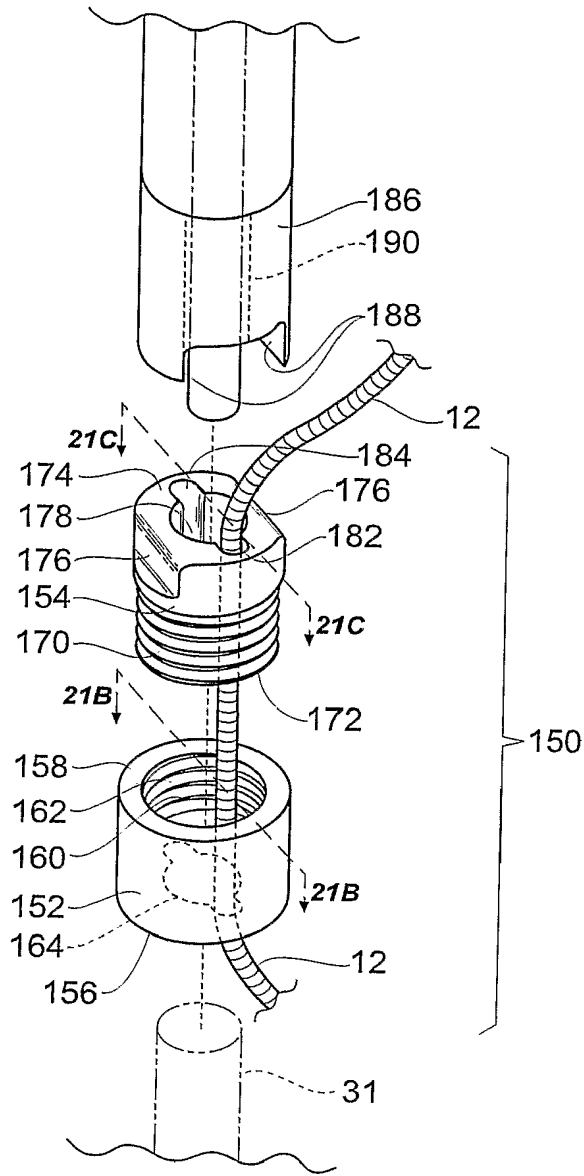


Fig. 44A

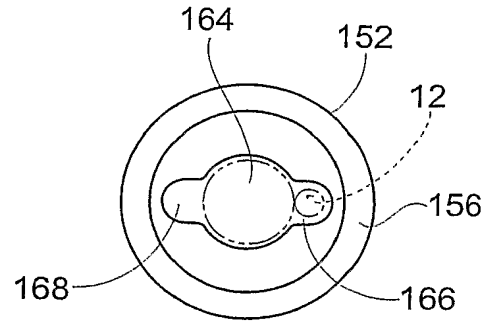


Fig. 44B

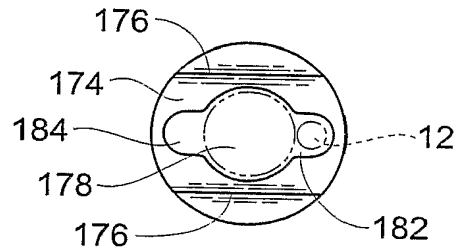


Fig. 44C

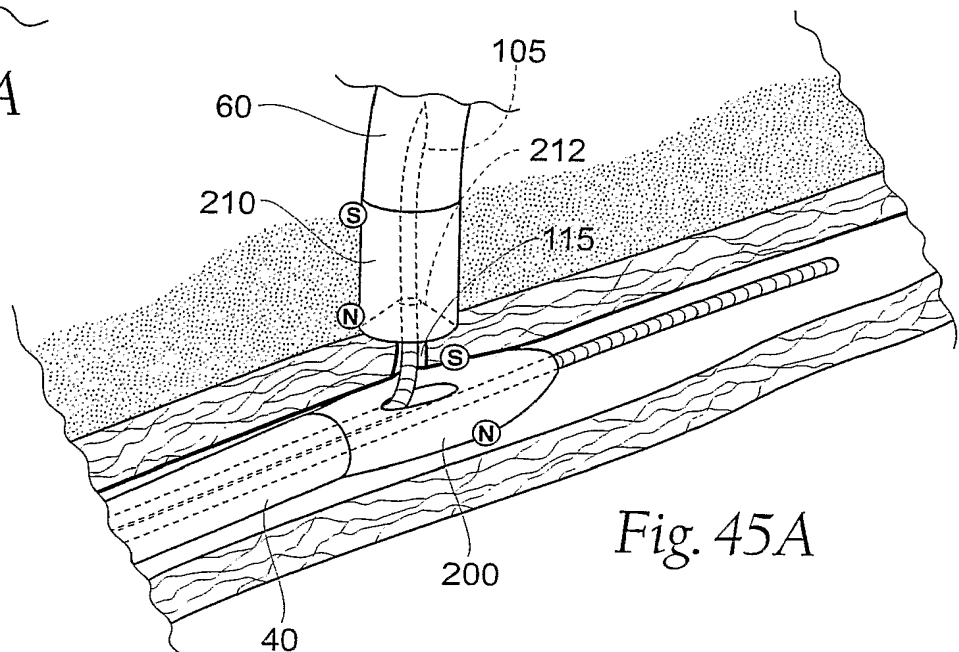


Fig. 45A

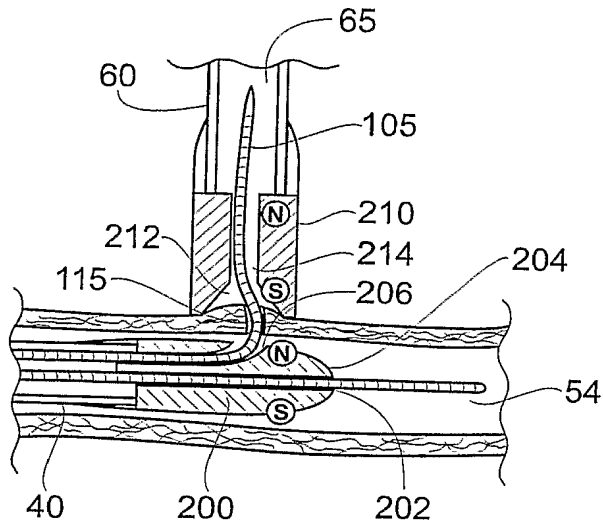


Fig. 45B

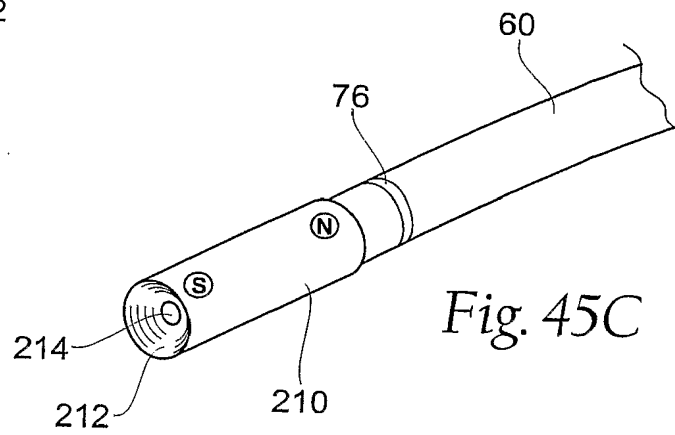


Fig. 45C

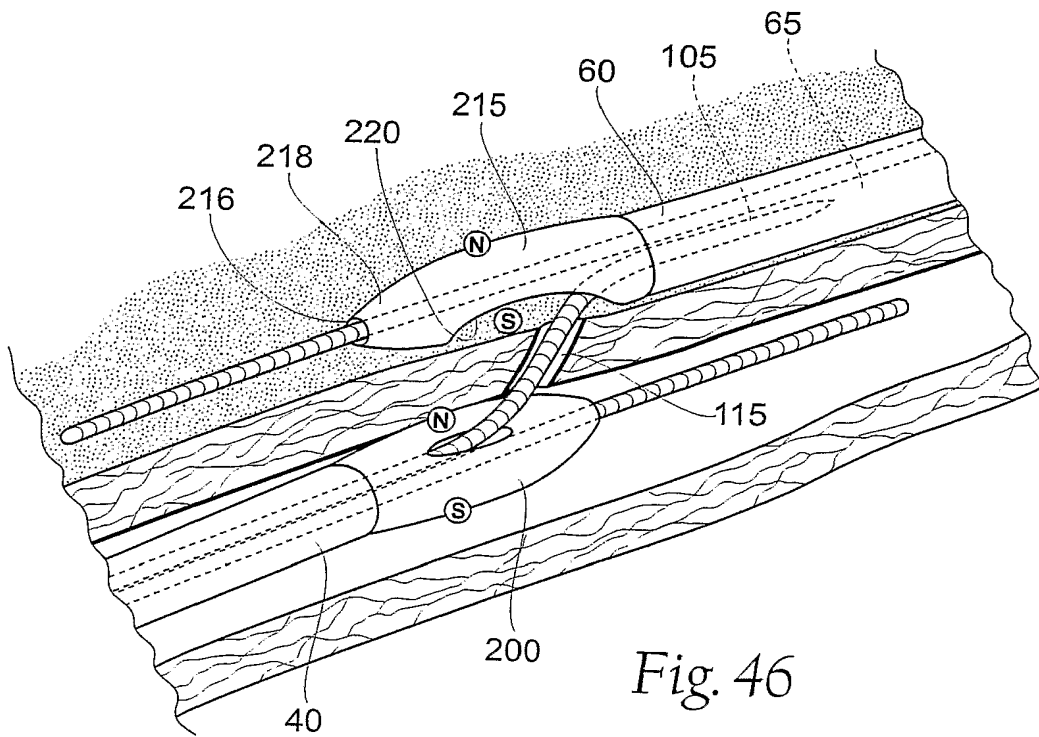


Fig. 46

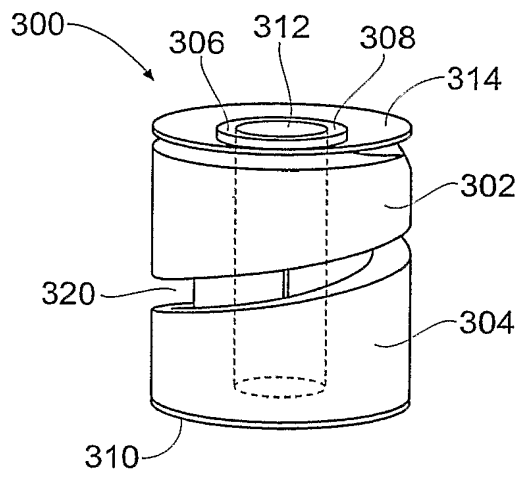


Fig. 47A

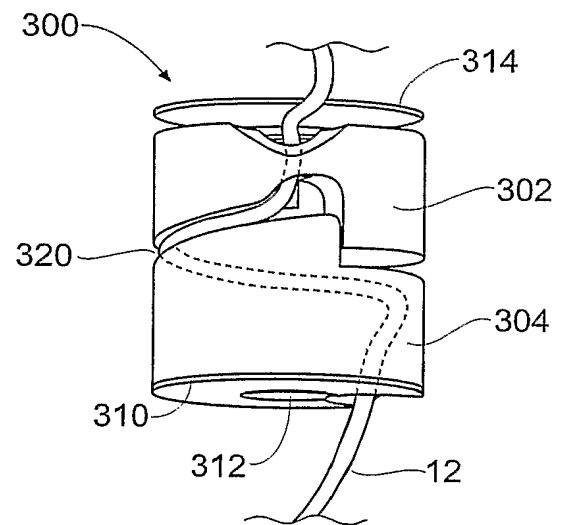


Fig. 47B

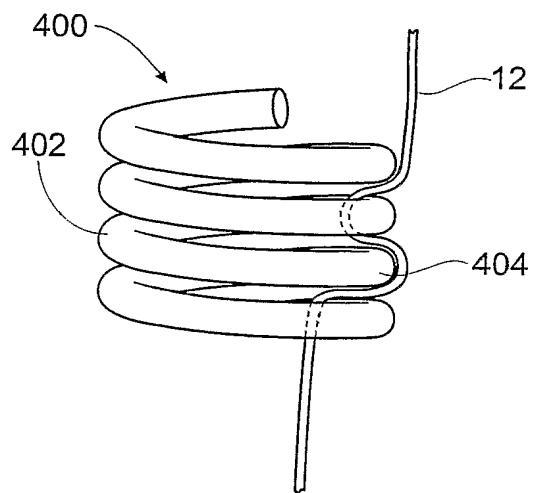


Fig. 48A

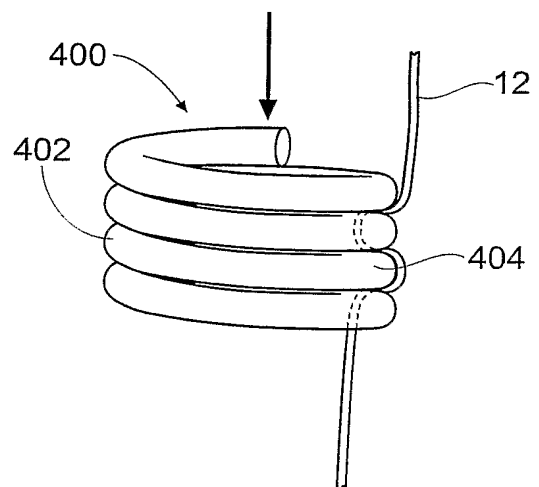
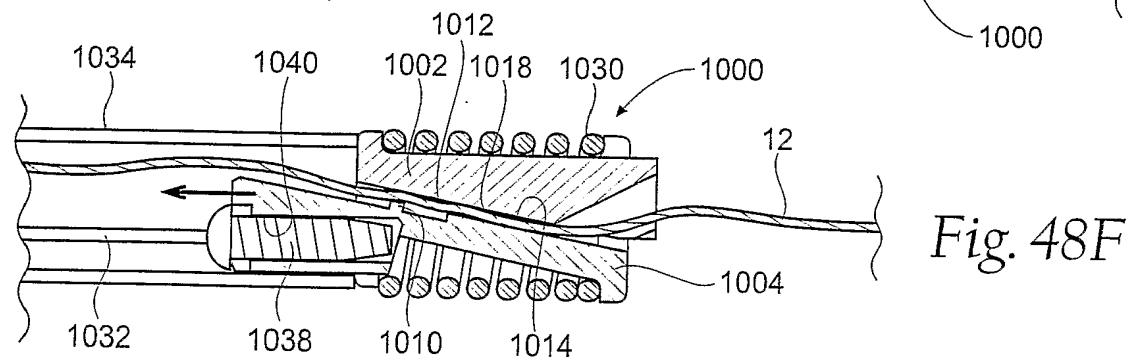
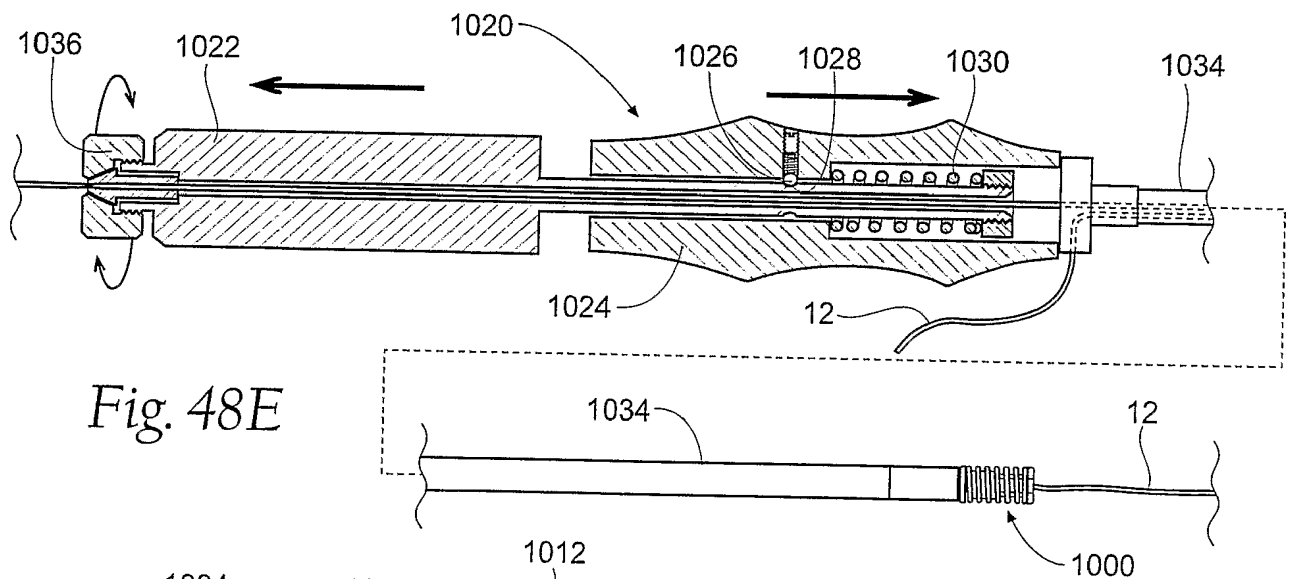
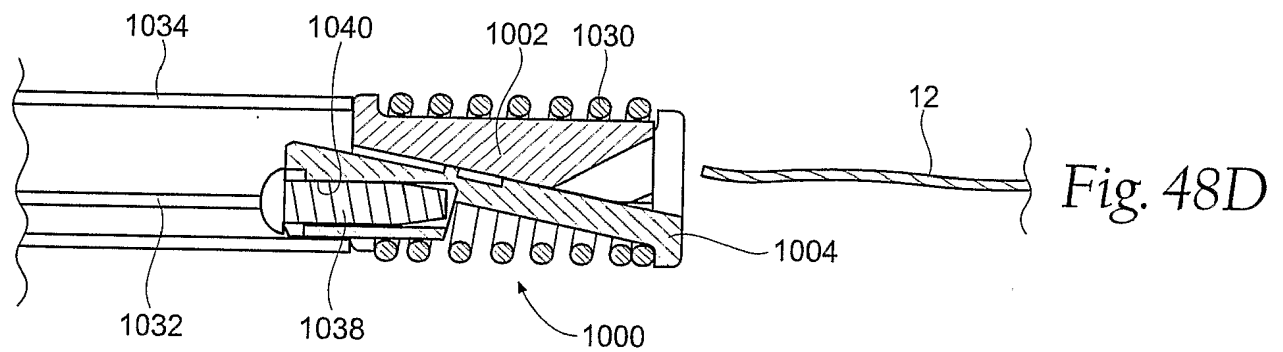
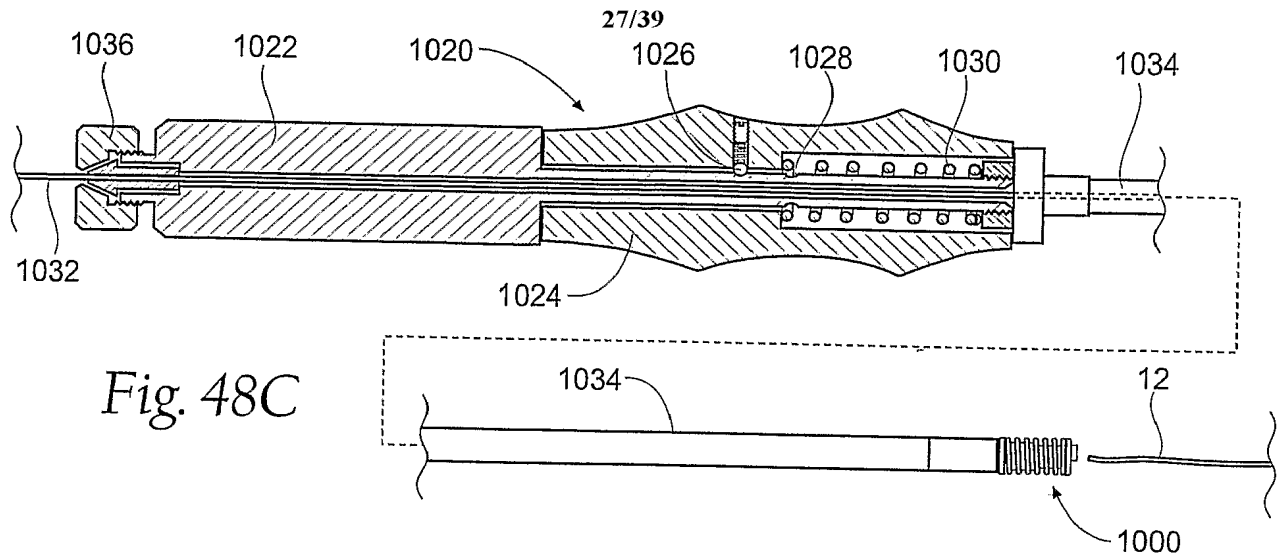


Fig. 48B



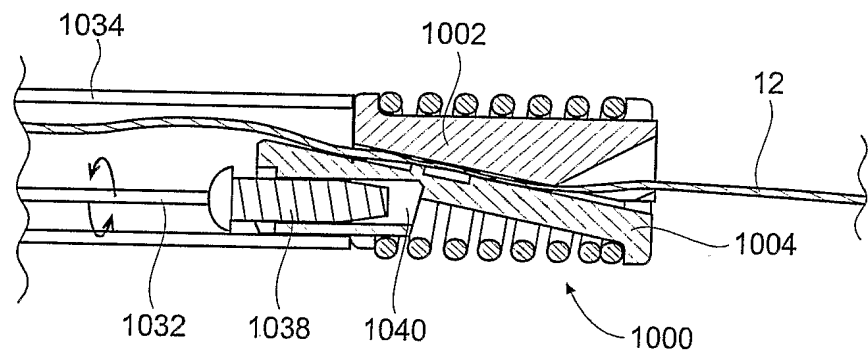
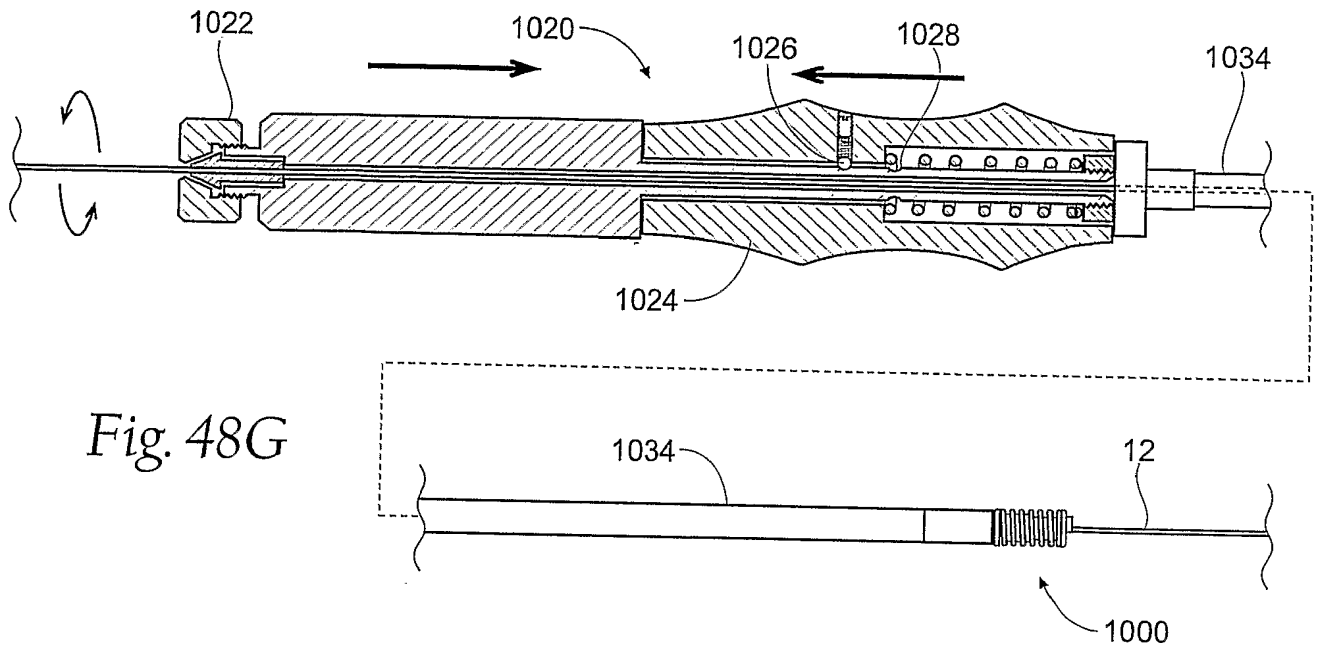


Fig. 48H

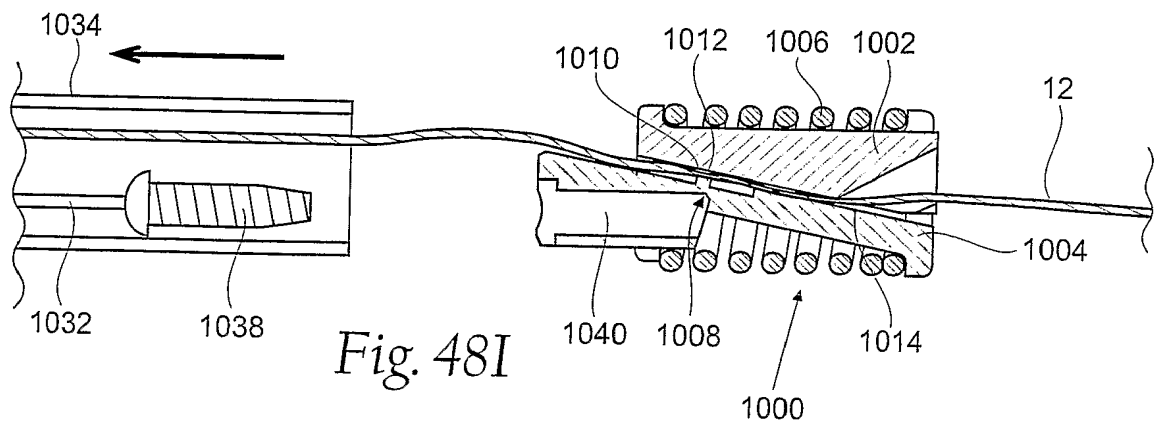
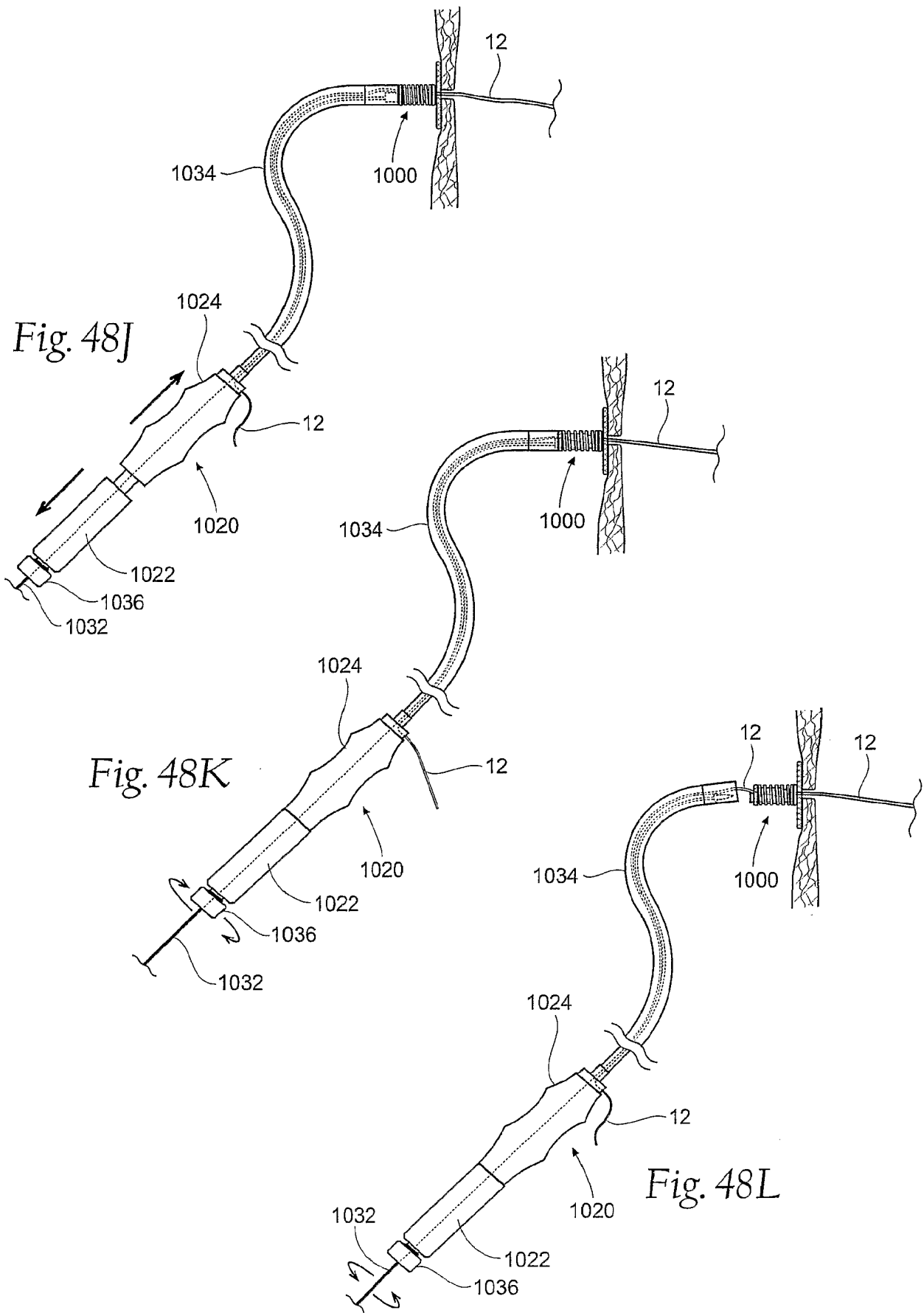


Fig. 48I



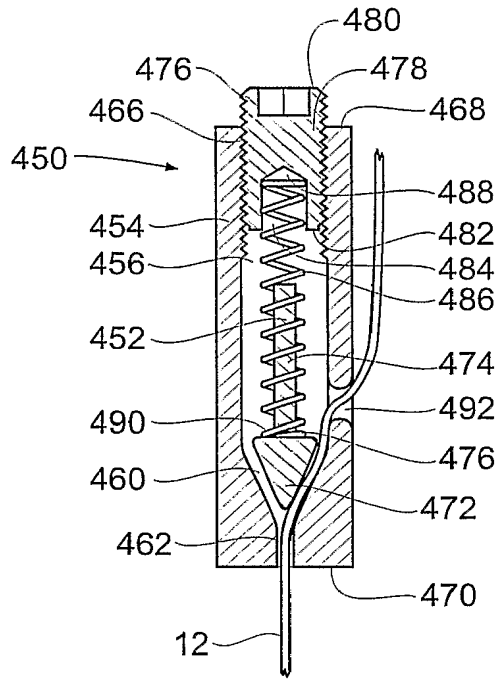


Fig. 49

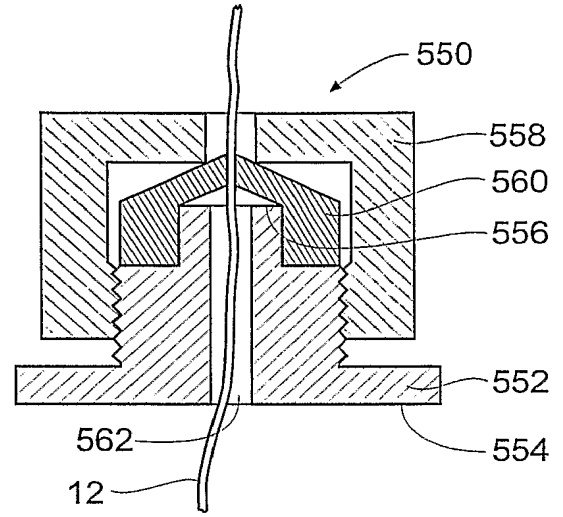


Fig. 50

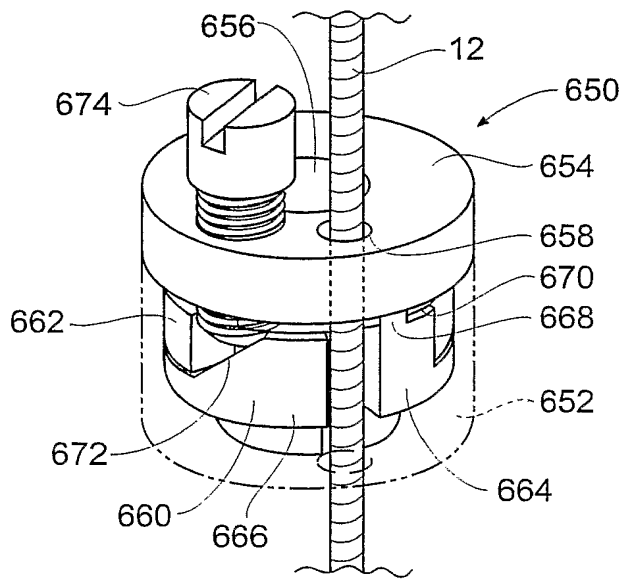


Fig. 51

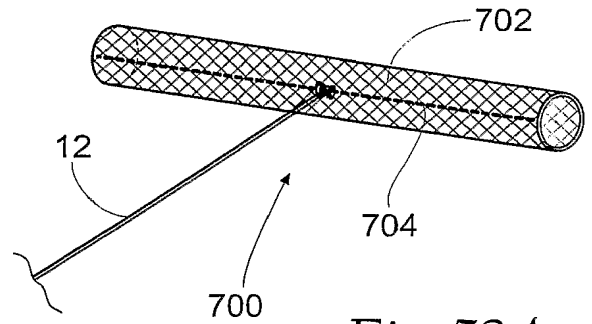


Fig. 52A

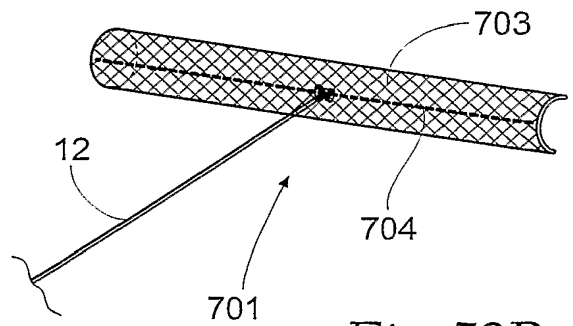


Fig. 52B



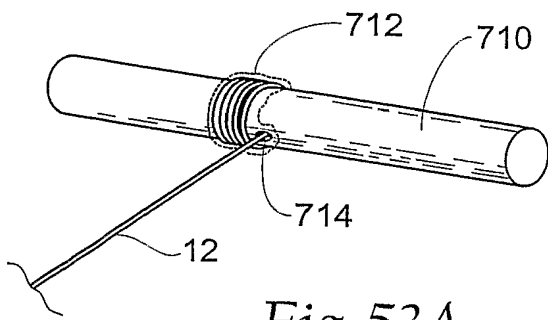


Fig. 53A

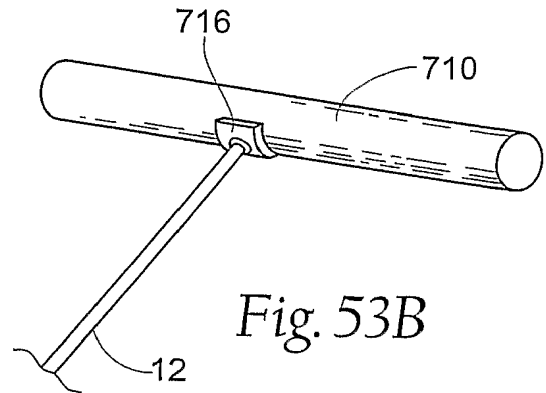


Fig. 53B

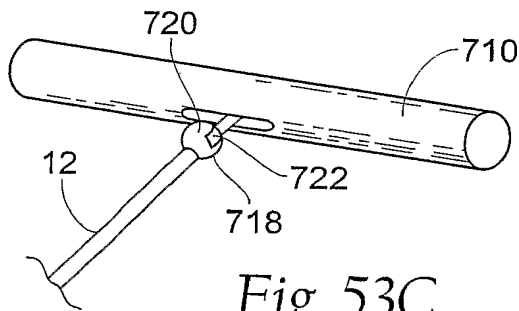


Fig. 53C

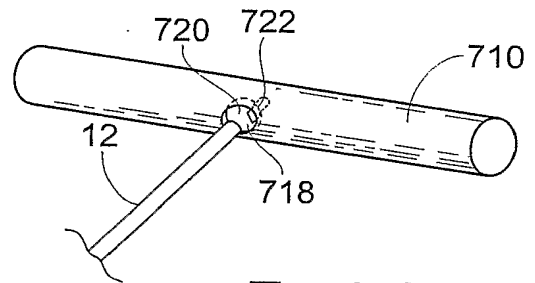


Fig. 53D

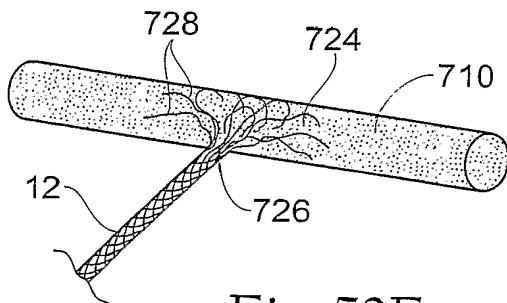


Fig. 53E

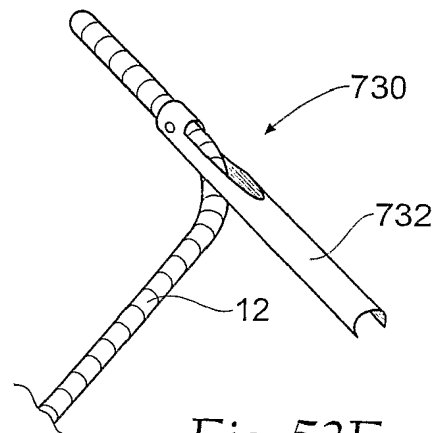
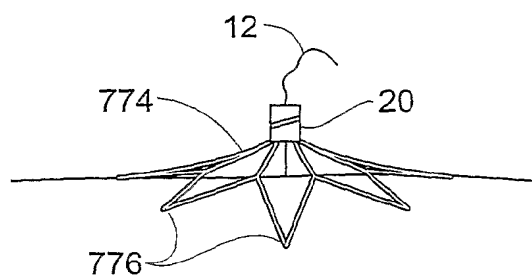
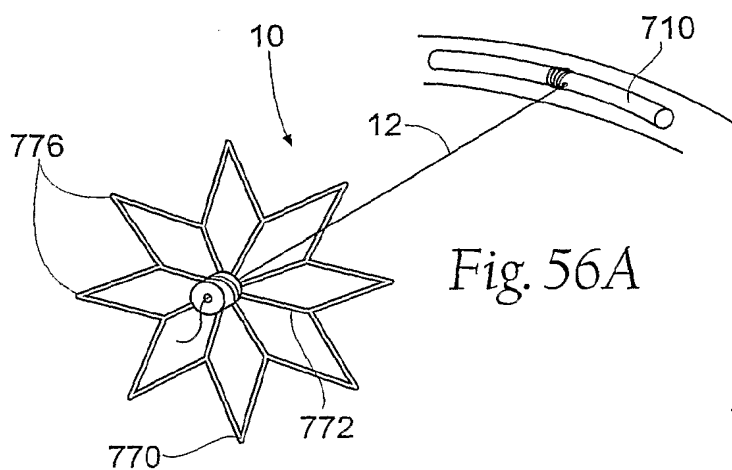
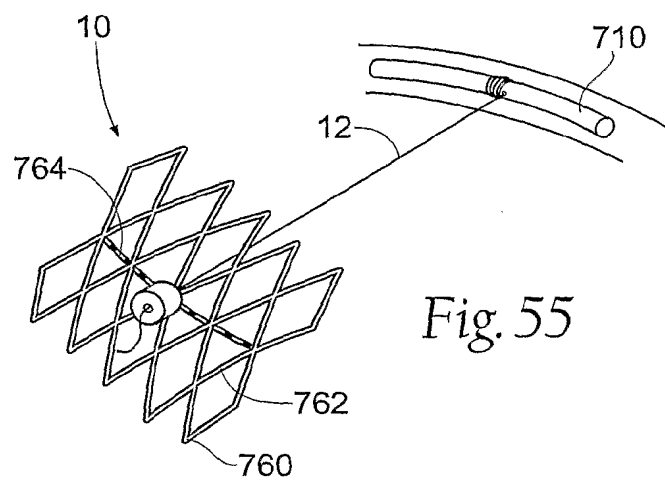
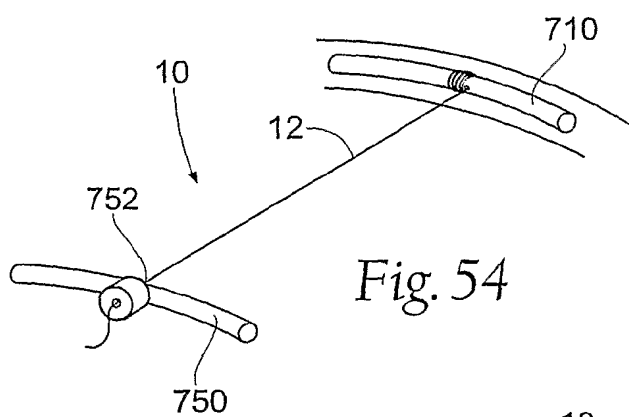


Fig. 53F



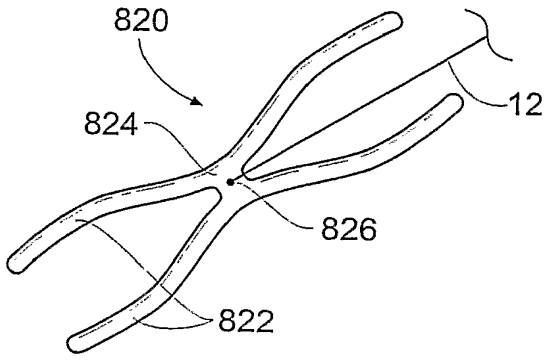


Fig. 57

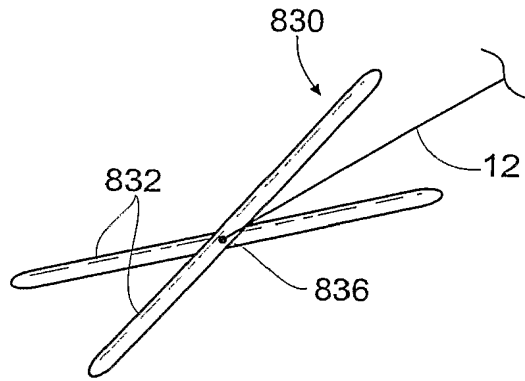


Fig. 58

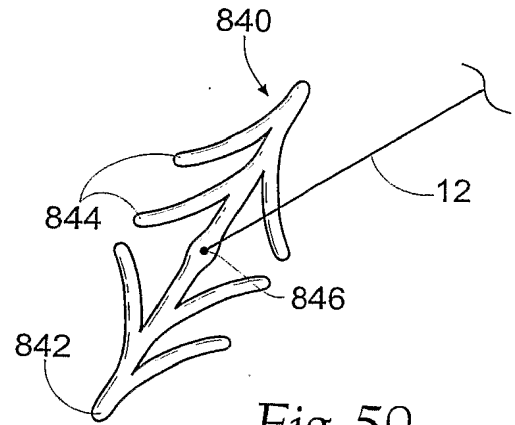


Fig. 59

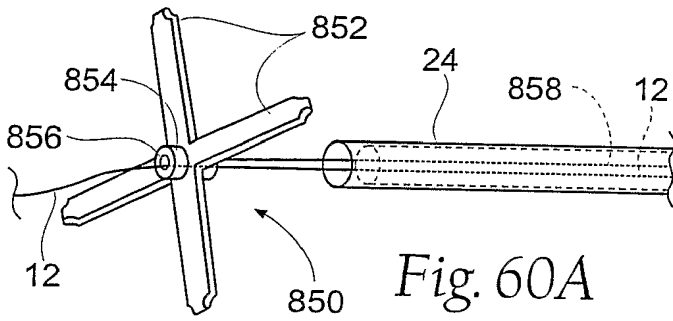


Fig. 60A

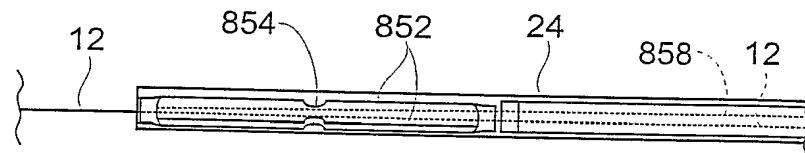
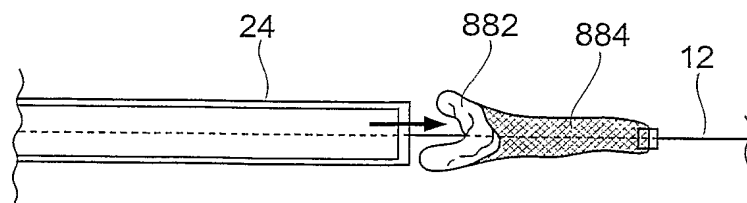
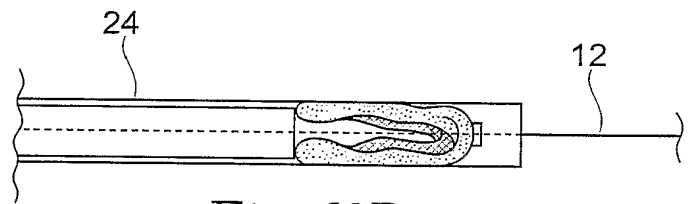
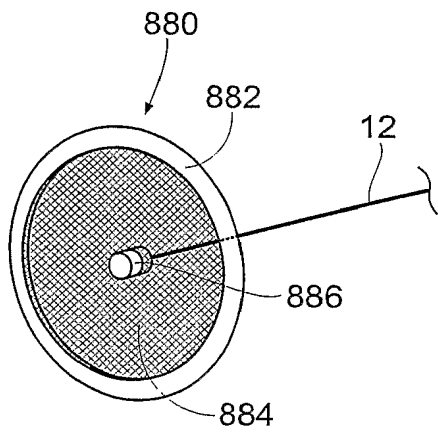
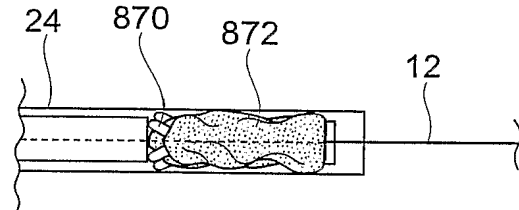
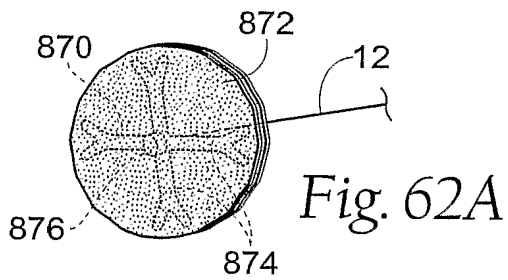
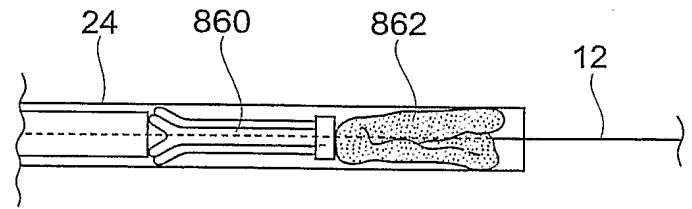
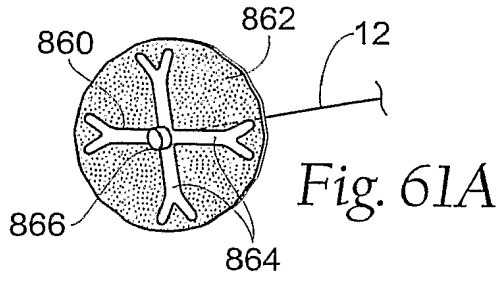


Fig. 60B



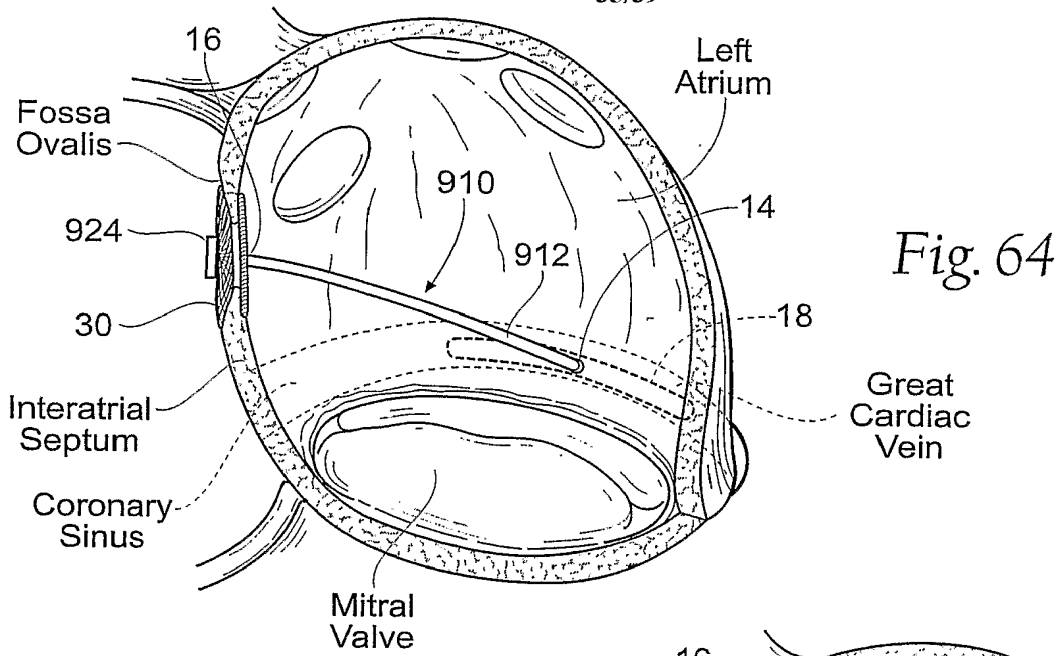
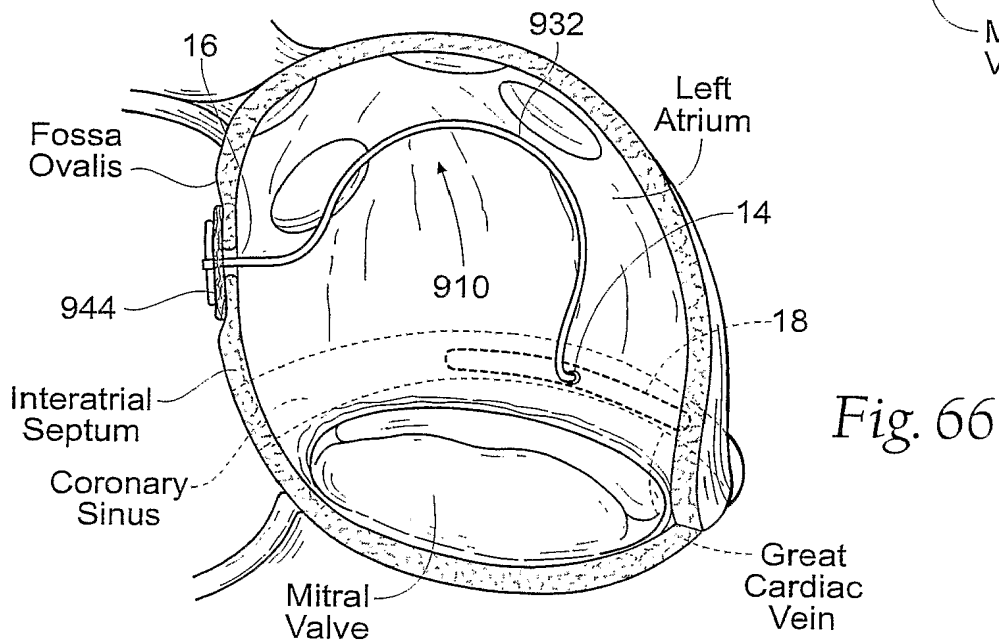
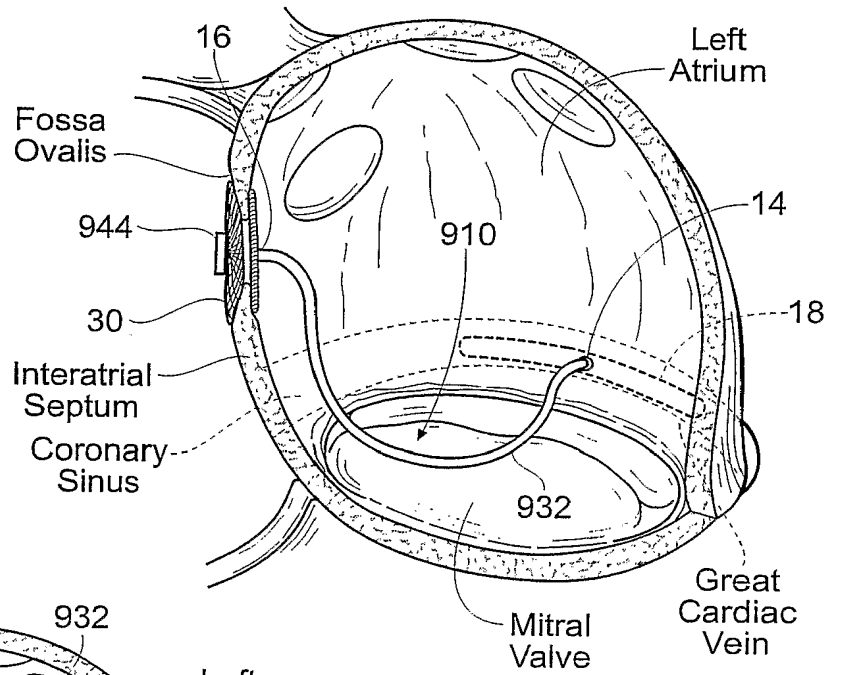
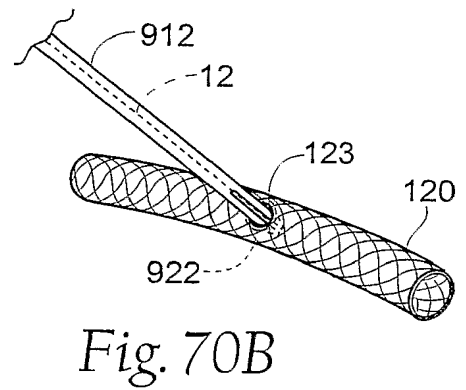
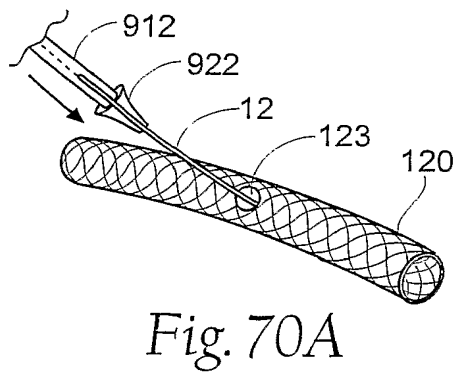
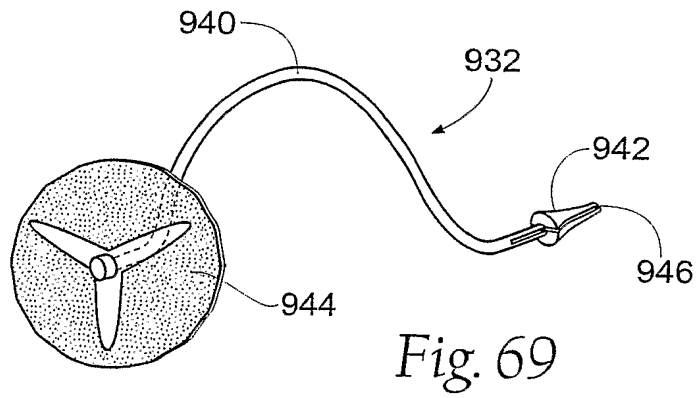
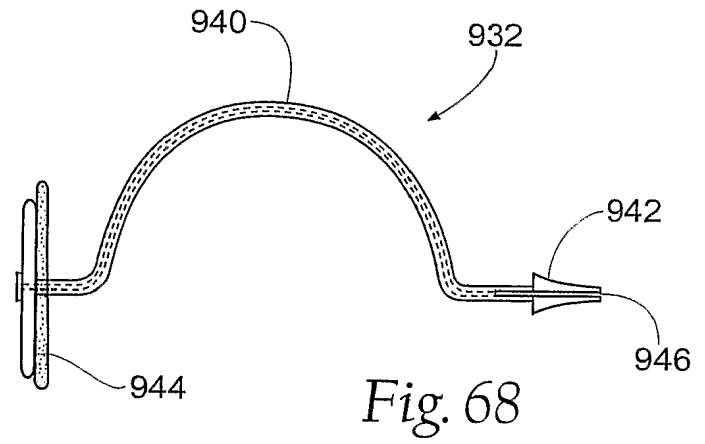
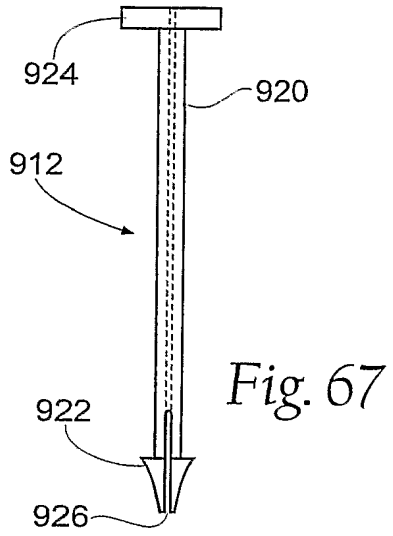


Fig. 65





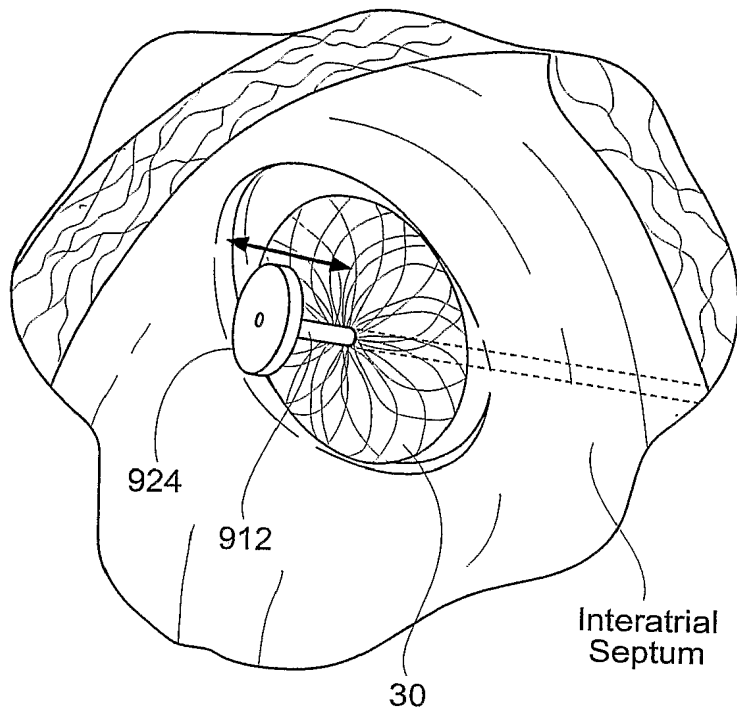


Fig. 71A

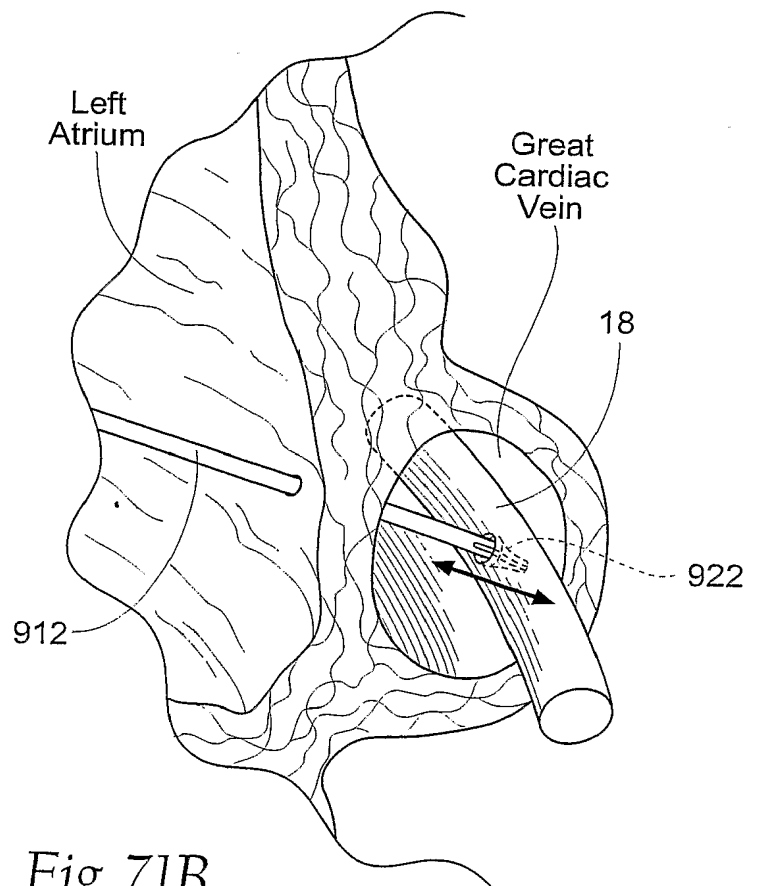


Fig. 71B

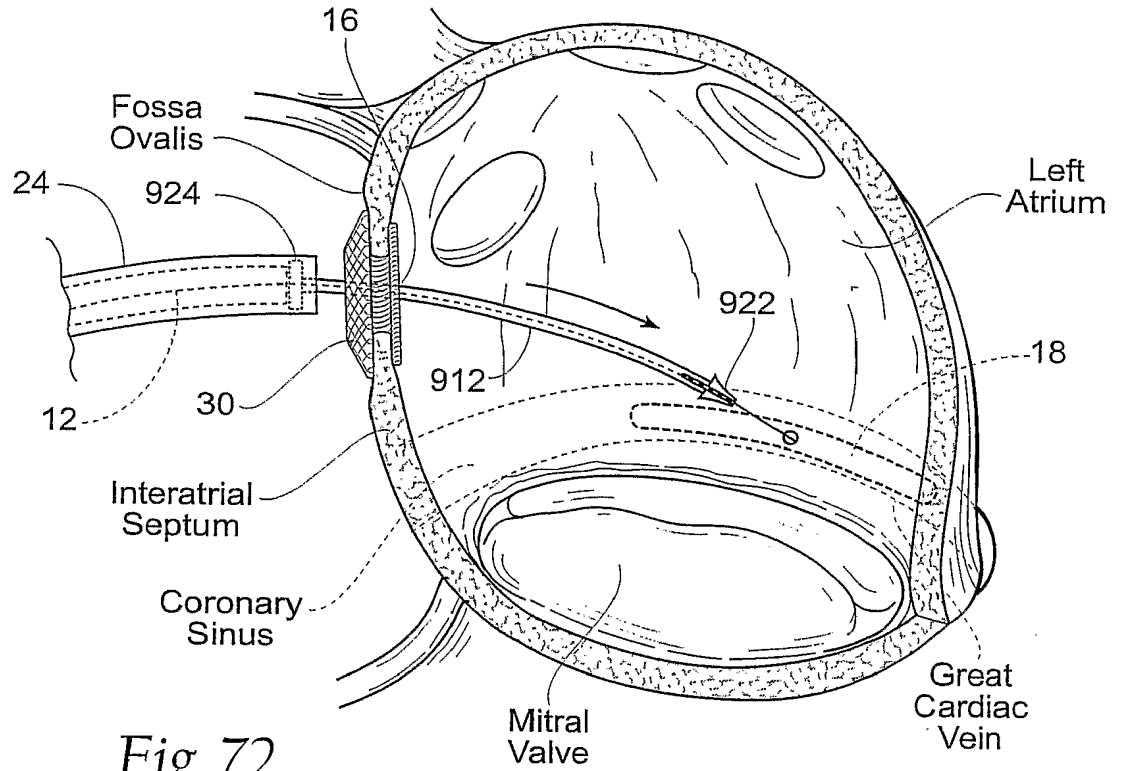


Fig. 72

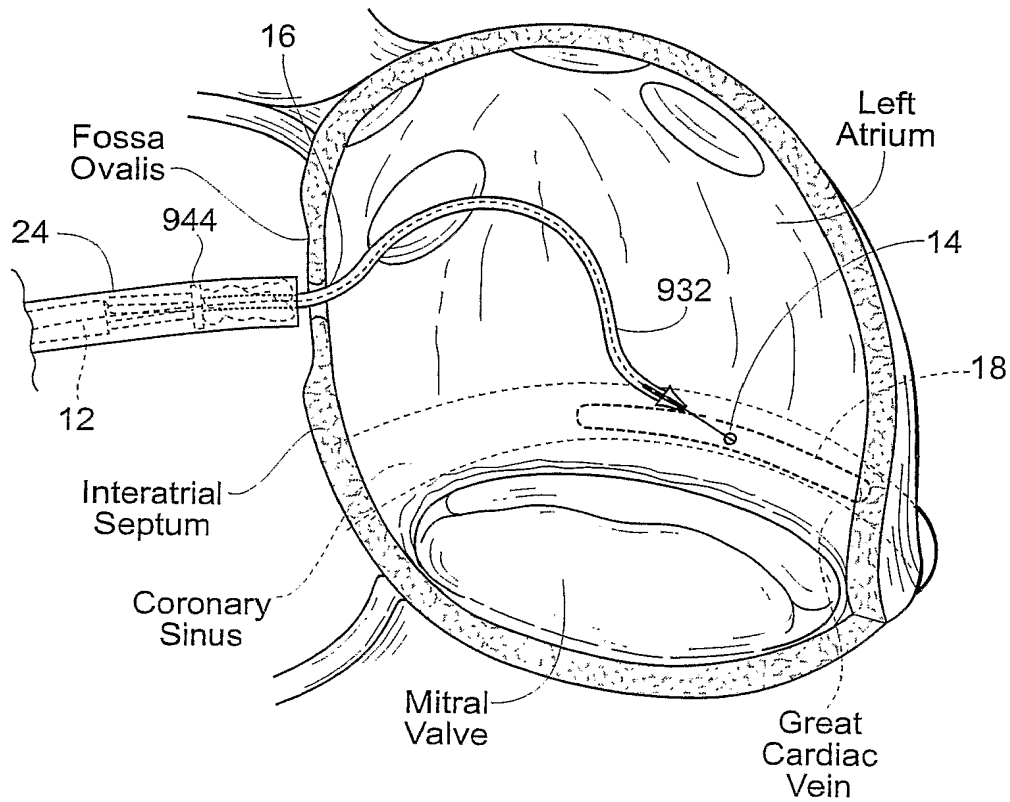
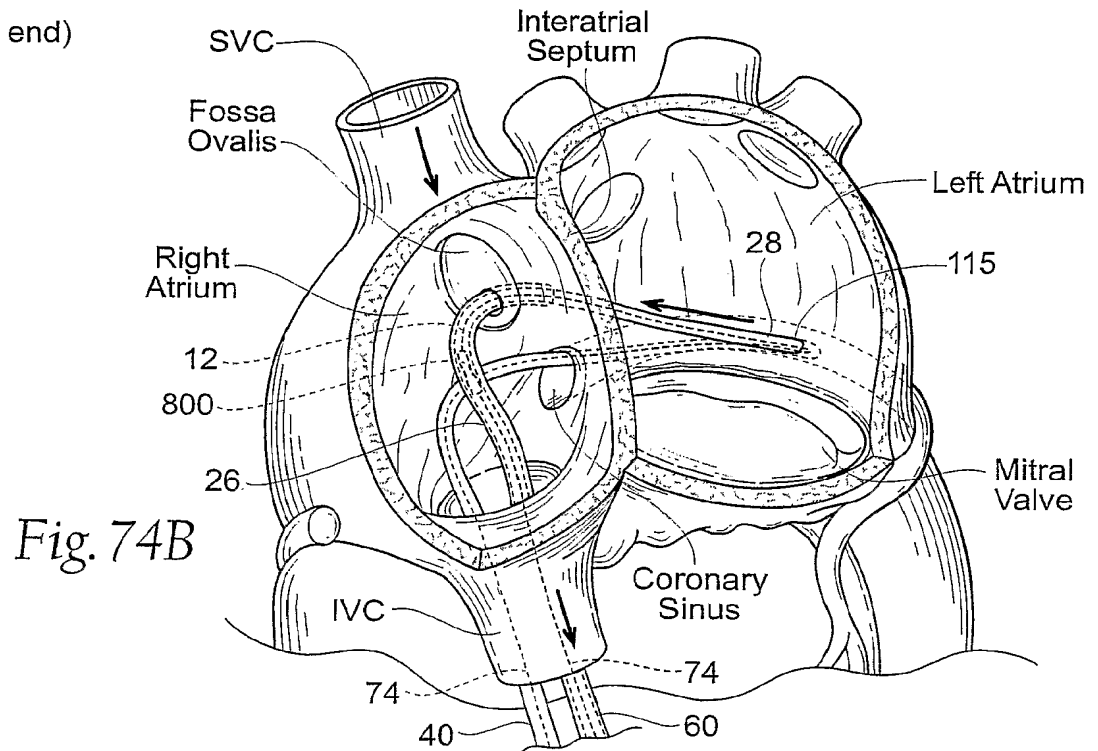
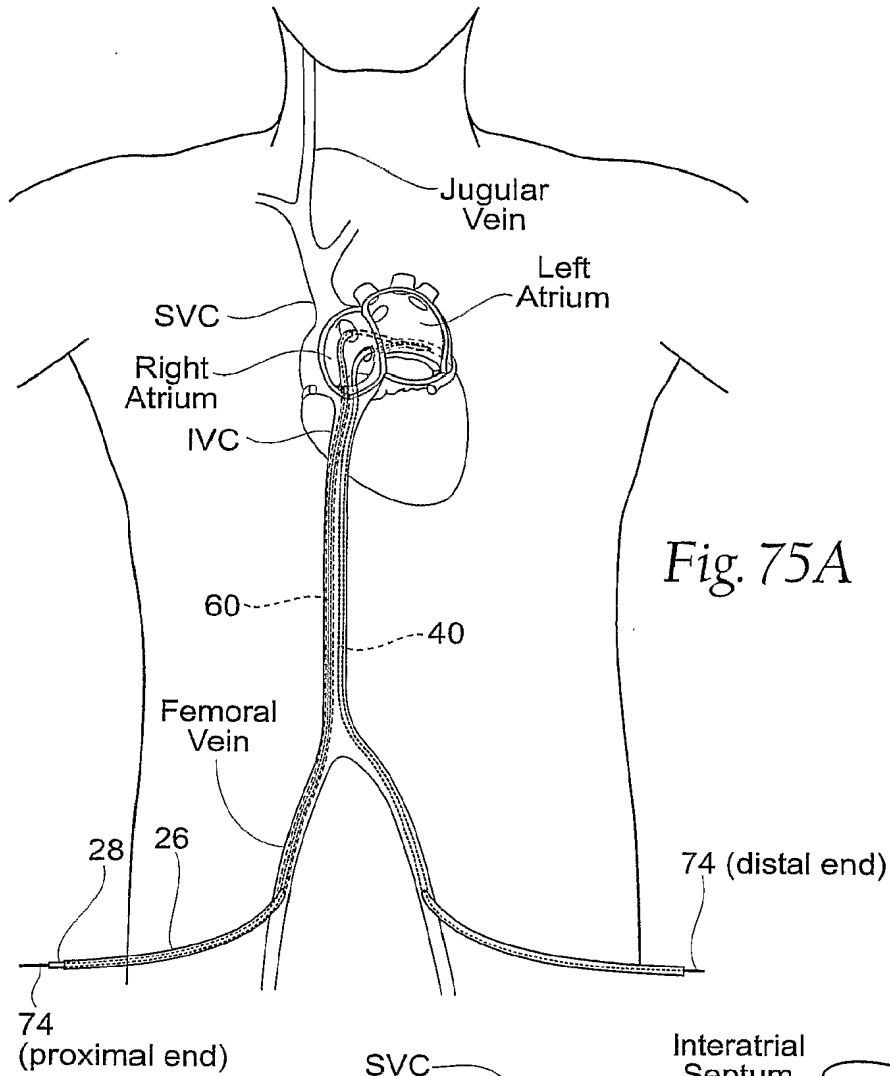


Fig. 73





# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US06/11086

## A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61F 2/24( 2006.01)

USPC: 623/2.36

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
U.S. : 623/2.36

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0010277 A1 (CHUTER) 13 January 2005 (13.01.2005), Paragraphs 22-24 and 103, Figures 6 and 7.	1-38

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

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document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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document member of the same patent family

Date of the actual completion of the international search  
21 June 2006 (21.06.2006)

Date of mailing of the international search report

31 JUL 2006

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (571) 273-3201

Authorized officer

For  
Corrine McDermott

Telephone No. (703)308-1148